



# Product Performance Report 1st Edition 2022

Cardiac Rhythm Management  
Cumulative Survival Probability

**Product**  
**Performance Report**  
**1st Edition 2022**

Cardiac Rhythm Management  
Pacemakers  
ICDs  
Leads

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# Quality Excellence

BIOTRONIK has a long history of high quality in product design and performance. For more than 50 years, the name BIOTRONIK has been synonymous with excellent workmanship and reliable patient safety. Our quality concept follows an integrated approach and extends from preventative risk measures during a product's development phase through all the steps of the manufacturing and design process.

BIOTRONIK's quality assurance system guarantees strict adherence to internal quality standards as well as compliance with international standards and guidelines. Regular reviews of our product performance and manufacturing evaluations contribute significantly to the achievement of extraordinary quality. Our customers, patients, and physicians can rely on the highest degree of safety built into our products. We always welcome suggestions from users about how we can improve the quality of our products.

This Product Performance Report is an integral component of BIOTRONIK's commitment to provide detailed, accurate information regarding long term reliability. The Product Performance Report exemplifies BIOTRONIK's policy of transparent and timely communication with our customers.

As a means to obtain continuous improvement of the designs, BIOTRONIK carefully analyzes returned products and incorporates all findings into our quality assurance system. This Product Performance Report was prepared in accordance with International Standard ISO 5841-2: 2014 (E)<sup>1</sup> and is in compliance with the recommendations from the U.S. Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. As an active member of AdvaMed and their Pacemaker/ICD Working Group, BIOTRONIK has worked extensively with the CRM industry to ensure comparable product performance data is reported by all manufacturers.

The data provided in BIOTRONIK's Product Performance Report incorporates the requirements and definitions as defined in AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators, except as noted herein.

In BIOTRONIK's continuous efforts to provide accurate and transparent information and to ensure that a conservative estimate for device performance is reported, the Survival Probability calculations presented herein also consider reported pacemaker and ICD battery depletions as well as lead complications without the device having been returned for analysis.

<sup>1</sup> The ISO 5841-2:2014(E) is replacing the previous version ISO 5841-2:2000. As part of the update, AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators were incorporated in the new ISO 5841-2:2014(E).

Because a significant portion of this report is based on analyses of returned products, BIOTRONIK urges all physicians to return explanted devices and to notify us when a product is explanted or no longer in use for any reason.

BIOTRONIK aims to continually improve and enhance the scope of this report while integrating the latest information and data concerning the performance of our products. Please contact Advanced Product Support (800) 547-0394 or the PPR Support Team at [ppr@biotronik.com](mailto:ppr@biotronik.com) with any comments, suggestions or questions regarding this report. Your feedback is highly appreciated and will be used to further develop this report.

BIOTRONIK, May 2022



A handwritten signature in dark ink, reading "R. Borkowski".

**Roman Borkowski**  
Senior Vice President  
Quality Management  
& Regulatory Affairs CRM  
BIOTRONIK SE & Co. KG



## **Terms and Definitions**

# 1. Terms and Definitions

The following terms and definitions are used for pacemakers and implantable cardioverter-defibrillators (ICDs) as well as pacing and ICD leads throughout this Product Performance Report. These definitions form the basis for this Product Performance Report by clearly articulating the status of each device return and product analysis classification.

## **Elective Replacement Indicator**

All active implantable devices that are powered by an internal battery need to be replaced when their battery is depleted. BIOTRONIK pacemakers and ICDs have an Elective Replacement Indicator (ERI) feature aka Recommended Replacement Time (RRT) that notifies the health care provider when the device's battery is nearing the end of its useful life. Display of ERI is BIOTRONIK's recommendation to the user that the battery's present state will require device replacement in the near future. For further details please refer to the corresponding manual.

## **Battery Depletion**

Battery depletions are classified as either normal (expected) or premature. Premature battery depletions are defined as device malfunctions, while normal battery depletions are not device malfunctions. Batteries of returned devices are considered to have depleted normally when (a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or (b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using the longevity calculation tool available at time of product introduction, calculated using the device's actual use conditions and settings.

For consistency with previous Product Performance Reports, for ICDs released prior to Lumax and pacemakers released prior to Philos II, batteries of returned devices are considered to have depleted normally if they have reached their elective replacement indicator and testing indicates that the battery and associated circuitry are within specifications.

## **Out of Specification**

Any component or software related event that causes the device's characteristics to not meet pre-defined performance specifications and requirements while implanted and in service. Returned product analysis that determines a device to be out of specification is considered a device malfunction. Normal battery depletions are not considered device malfunctions. BIOTRONIK defines the requirements and performance specifications for each product.

## **Device Malfunctions**

Any component or software related event that causes the device's characteristics to be out of specification while implanted and in service are considered as device malfunctions. Because it is impossible to verify that a device has malfunctioned without analyzing it, only returned devices can be classified as malfunctions for this report. Each returned lead, ICD and pacemaker is analyzed to determine if it has malfunctioned. If the analysis determines that a pacemaker or ICD failed to meet its specifications while implanted and in service, it is further classified as either a malfunction with compromised therapy or as a malfunction without compromised therapy. Devices damaged during implant, revision or after explant, damaged due to external causes (i.e. electrocautery) or due to failure to follow instructions, warnings or contraindications in its associated

technical manual are not considered malfunctions. Devices damaged due to interaction with other implanted devices (i.e., leads) are also not considered as malfunctions for the purposes of this Product Performance Report.

## **Malfunctions with Compromised Therapy**

The condition when a pacemaker or ICD is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if critical patient-protective pacing or defibrillation therapy is not available.

Examples include: sudden loss of battery voltage; accelerated current drain such that a depleted battery was not detected before loss of therapy; sudden malfunction during a tachycardia or fibrillation event resulting in aborted delivery of therapy; intermittent malfunction where therapy is sporadically unavailable.

## **Malfunctions without Compromised Therapy**

The condition when a pacemaker or ICD is found to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Therapy is not compromised as long as critical patient-protective pacing and defibrillation therapies are available as determined through device analysis.

### **Lead Complications**

A lead performance issue where a complaint, associated with at least one of the clinical manifestations listed below, is reported and where the non-returned lead is:

- Verified by medical records to have been implanted and in-service, and
- Reported to have been removed from service,
- Modified to remedy the malfunction, or
- Left in service based on medical judgment.

Complications for leads implanted greater than 30 days are reported as qualifying lead complications, whereas complications occurring during the first 30 days are reported as acute lead observations.

In accordance with the latest AdvaMed guidelines and ISO 5841-2:2014(E), the complications are classified in the following categories:

- Failure to Capture
- Failure to Sense
- Oversensing
- Abnormal Pacing Impedance
- Abnormal Defibrillation Impedance
- Insulation Breach
- Conductor Fracture
- Lead Dislodgement
- Extracardiac Stimulation
- Cardiac Perforation
- Other

### **Survival Probability Estimates**

The probability that a device remains operational during a discrete time interval is defined as survival probability. Survival probability, as presented in this report, is related to device survival only and not survival of the patient. The survival probability

estimates in this report are based on BIOTRONIK's analysis of returned products as well as events that are reported to BIOTRONIK (e.g., battery depletions or lead complications).

### **Cumulative Survival Probability Estimates**

The survival probability over a device's service time is the cumulative survival probability. It is calculated from all discrete survival probabilities of previous time intervals. This characteristic is calculated separately for malfunction-free survival and all-cause survival (including normal battery depletions). Specific populations that are subject to a safety advisory notification are excluded and shown separately.

### **Implanted Devices**

Only devices remaining implanted for at least one calendar day after the implantation date are considered as implanted. Devices that are removed from the patient on the same calendar day as the implant procedure do not contribute to the survival statistics.

### **Active Implants**

The number of devices that remain operational within a discrete observation interval are active implants. Units are removed from this cohort due to patient death or explant for any reason.

### **Underreporting**

A device status may change without being accounted for in the Product Performance database due to a lack of information being provided to BIOTRONIK. Underreporting adjustments deemed to be necessary are detailed in this report.

### **Safety Advisory Notifications**

Any action taken by the manufacturer to inform clinicians concerning a device performance issue that may cause the device to not meet its predefined specifications is referred to as a Safety Advisory Notification.





## **Methodology for Pacemaker and ICD Survival Estimates**

## 2. Methodology for Pacemaker and ICD Survival Estimates

### 2.1 Cumulative Survival Probability

This report has been prepared in accordance with ISO 5841-2:2014(E) applying actuarial analysis for the calculation of survival probabilities. Survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK devices.

The cumulative survival probability is an estimate based on the percentage of pacemakers and ICDs that remain implanted and operational at various points of the product's service time in absence of concurrent events such as morbidity and voluntary explants for various reasons (e.g., device upgrade). The device survival estimate over time is displayed in cumulative curves (Kaplan-Meier). The product's performance is evaluated in discrete one-month intervals. The survival probability for each month is given by the number of devices that remain implanted and operational through this month divided by the number of devices that entered the interval. The cumulative survival probability for any period is given by multiplying all survival probabilities of previous months.

At the time of implantation, the cumulative survival probability is 100 %. Even though they are analyzed as part of our quality system monitoring, devices that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time. Because this report is provided to describe product performance based on returned product analyses, the pacemaker and ICD data does not include information regarding medical complications such

as erosion, infection or diaphragmatic stimulation.

In general, during the initial phase of the service time, devices which are out of specification are the primary contribution to reduction of survival probability. As the product lifecycle lengthens, normal battery depletion assumes a greater impact on the survival curve and becomes the dominating factor.

In order to make these two effects distinguishable, the cumulative survival probability curves are shown separately for devices that are confirmed to have malfunctioned only, and for total (all-cause) cumulative survival. In case of a device being subject to a safety advisory notification that significantly impacts the survival probability, this factor is displayed separately.

### 2.2 Data Acquisition

This report is based on the observation of BIOTRONIK's U.S. products through review of our device registration and tracking systems and analyses of returned products from all sources. Because the ability to perform decedent searches of patients with BIOTRONIK devices via the U.S. Social Security Administration, the use of U.S. data more accurately represents the active patient population for reporting purposes. In addition, device tracking regulations and vigilance reporting regulations vary throughout the world; therefore, use of the U.S. data is most appropriate for accurate and consistent reporting of product performance.

In order to be included in the population under observation, a device must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is June 30, 2021. The number of U.S. devices that are implanted and remain

active as well as the total number of products distributed worldwide are provided for each product family in this report. Information is provided for separate product families, in that devices with nearly identical hardware and therapy functions are combined. For example, Edora 8 DR and DR-T (with Home Monitoring) IPGs are combined into a single family, Edora 8 Single Chamber IPGs.

Survival estimates are calculated for product families having accumulated at least 10,000 cumulative implant months. Because 10,000 implant months may take some time to accumulate, there may be a gap between U.S. market release and the start of graphical representation of survival probability. Products no longer being distributed with less than 500 active implants may be excluded from this report.

ISO 5841-2 describes a method for adjusting the device survival probability to compensate for underreported malfunctions and unrelated patient deaths. The factor for underreporting of malfunctions is unknown as currently no systematic data is available that reveals this factor. Consequently, this factor remains unaccounted for this report. Patient mortality is artificially elevated if the reported rate from our registration and tracking systems is below the annual mortality in clinical studies. Normal battery depletion rate is assumed if the reported rate of depletion decreases over time.

## 2.3 Returned Product Analysis

Information on malfunctioning for the pacemaker and ICD portions of this report is taken exclusively from the analysis of returned products. The outcome of this analysis is the basis for the final classification of the device's cause of explantation. Only analyzed products with confirmed device malfunctions are utilized in the calculation of malfunction-free survival probability.

Every pacemaker and ICD returned to BIOTRONIK is analyzed per internal procedures and classified as functioning normally, normal battery depletion, or malfunctioning (including premature battery depletion) while implanted and in service. These device classifications are the basis for BIOTRONIK's cumulative survival estimates on pacemakers and ICDs.

As a significant portion of pacemakers and ICDs with normal battery depletion are not returned for analysis, BIOTRONIK also considers unconfirmed pacemaker and ICD battery depletions (reported, but device not returned) in the total survival estimates to ensure that a conservative estimate for device performance is reported.

## 2.4 Product Performance Graphs and Data

The product performance information is shown in each section in alphabetical order and by product type.

For each product, the report provides:

- Product versions that contribute to the evaluation
- U.S. and CE market release dates
- Worldwide quantity of products that have been distributed
- U.S. registered implants (number of products included in this report)
- Estimated active U.S. implants
- Number of U.S. normal battery depletions
- Number of U.S. confirmed malfunctions

The survival plots provide:

### 1. Total Survival

The combined cumulative survival probability for all causes that result in device removal or a system out of operation, excluding removals for clinical reasons unrelated to the device's performance (i.e., infections).

### 2. Malfunction-Free Survival

The cumulative survival probability free of component or software malfunctions excluding normal battery depletions, but including premature battery depletions. Normal battery depletions only have an impact on the total cumulative survival.

Products or subgroups of products may become subject to safety

advisory notifications that can significantly impact the overall product performance. However, as these subgroups are clearly defined they are separated from the non-advisory devices. The impact of the advisory notification is then shown in a separate graph for total cumulative survival and for malfunction-free survival of the device population affected by the advisory notification. Current advisories are listed in chapter 11 of this report.

The cumulative survival data and the 95% confidence intervals according to the Greenwood's Formula<sup>1</sup> are shown in numerical form for the observed population.

<sup>1</sup> Greenwood, M. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1-26, 1926

## Performance of BIOTRONIK Pacemakers

- 3.1 Single-Chamber Pacemakers
- 3.2 Dual-Chamber Pacemakers
- 3.3 CRT Pacemakers

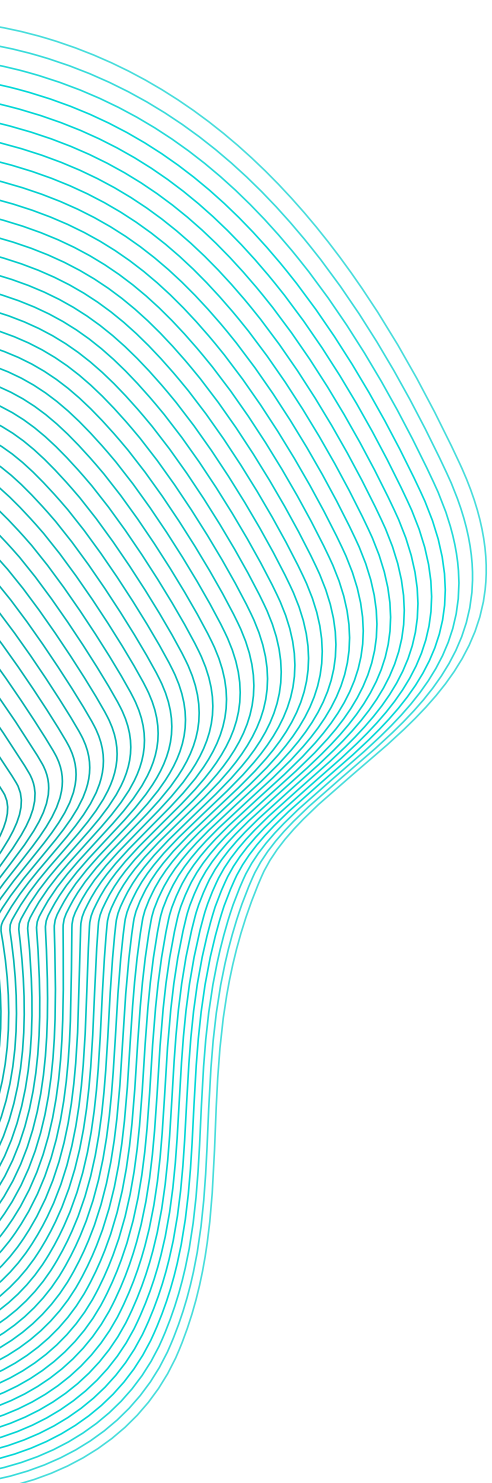


# Performance of BIOTRONIK Pacemakers

## 3.1 Single-Chamber Pacemakers

## 3.2 Dual-Chamber Pacemakers

## 3.3 CRT Pacemakers

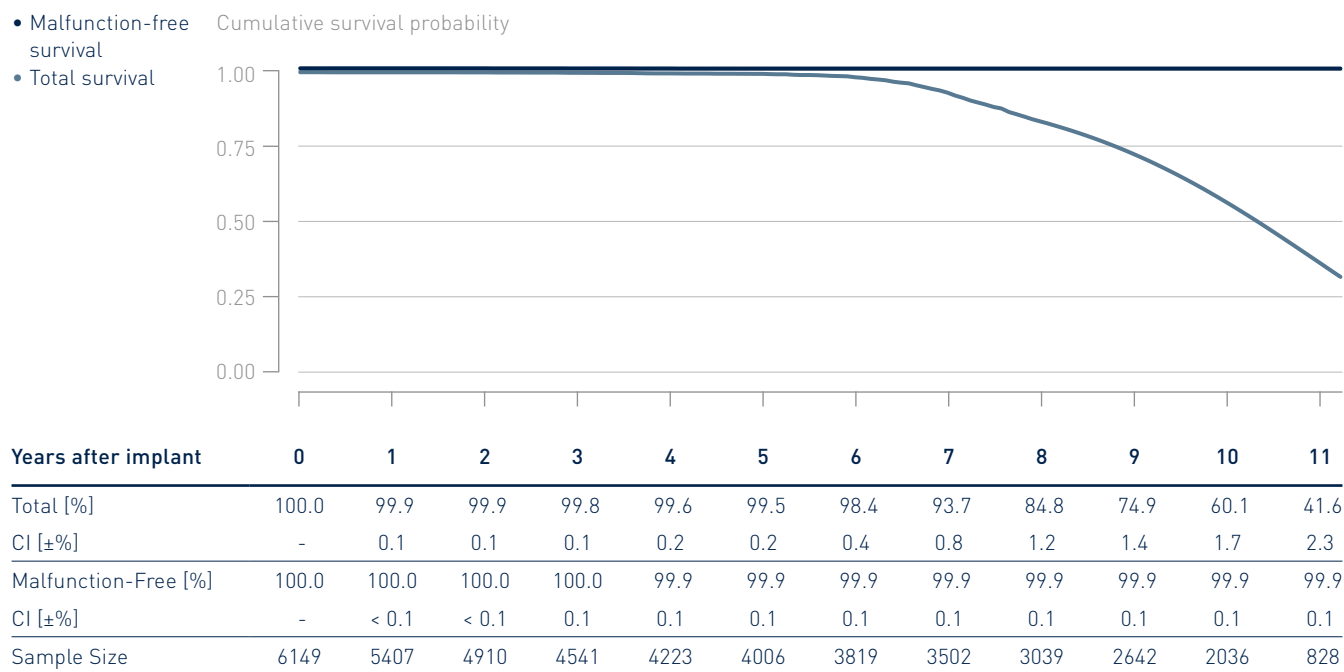


## 3.1 Single-Chamber Pacemakers

### Cylos and Cylos 990

Product Versions _____	VR
NBG Codes _____	VVIR
US Market Release _____	Jan 2006
CE Market Release _____	Nov 2005 / Mar 2008
Worldwide Distributed Devices _____	25 900
Registered U.S. Implants _____	6 149
Estimated Active U.S. Implants _____	2390
U.S. Normal Battery Depletions _____	851

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	4	0.07%
Therapy Compromised _____	1	0.02%
Therapy Available _____	3	0.05%

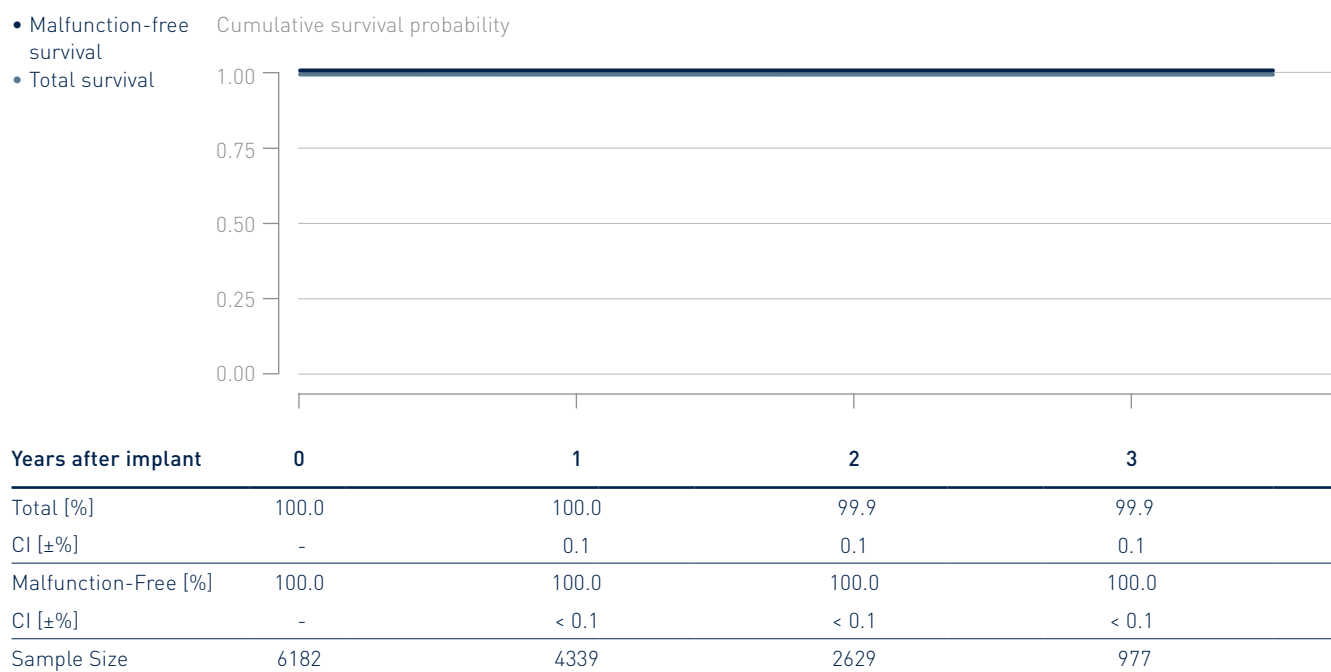


## 3.1 Single-Chamber Pacemakers

### Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	33300
Registered U.S. Implants	6182
Estimated Active U.S. Implants	5470
U.S. Normal Battery Depletions	3

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

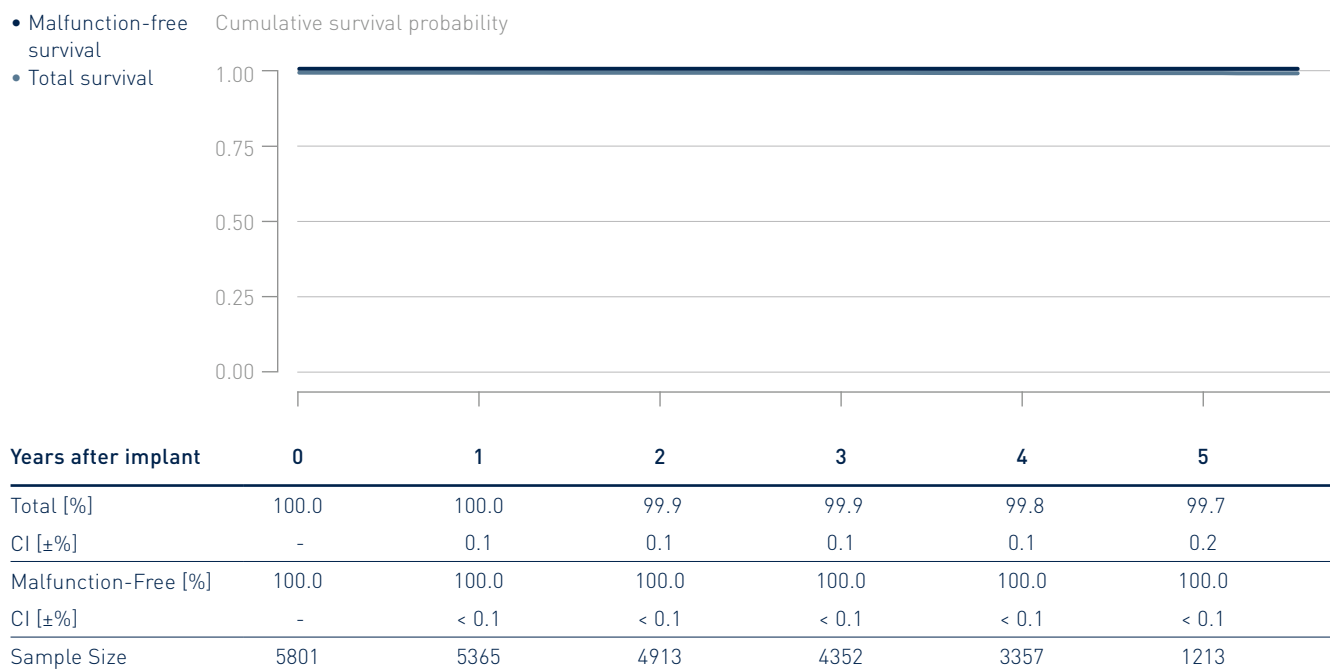


## 3.1 Single-Chamber Pacemakers

### Eluna 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	19 600
Registered U.S. Implants	5 801
Estimated Active U.S. Implants	4 420
U.S. Normal Battery Depletions	13

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



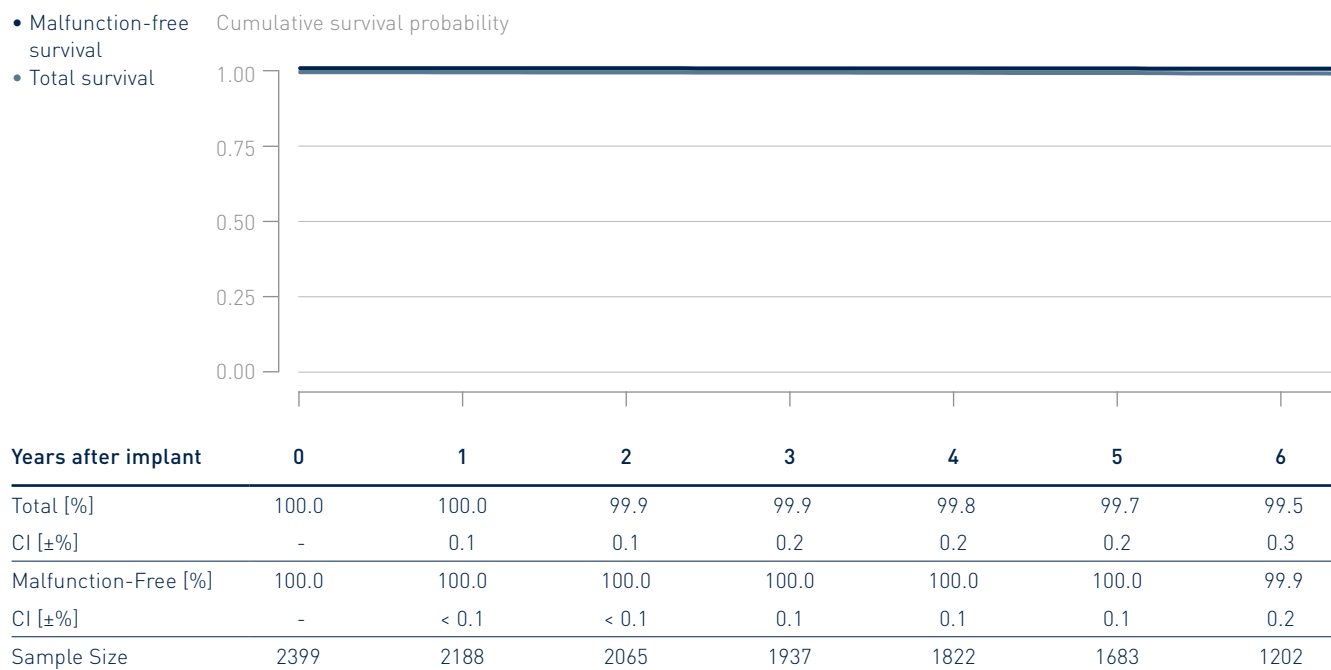


## 3.1 Single-Chamber Pacemakers

### Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28 000
Registered U.S. Implants	2399
Estimated Active U.S. Implants	1 660
U.S. Normal Battery Depletions	8

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	2	0.08%
Therapy Compromised	1	0.04%
Therapy Available	1	0.04%

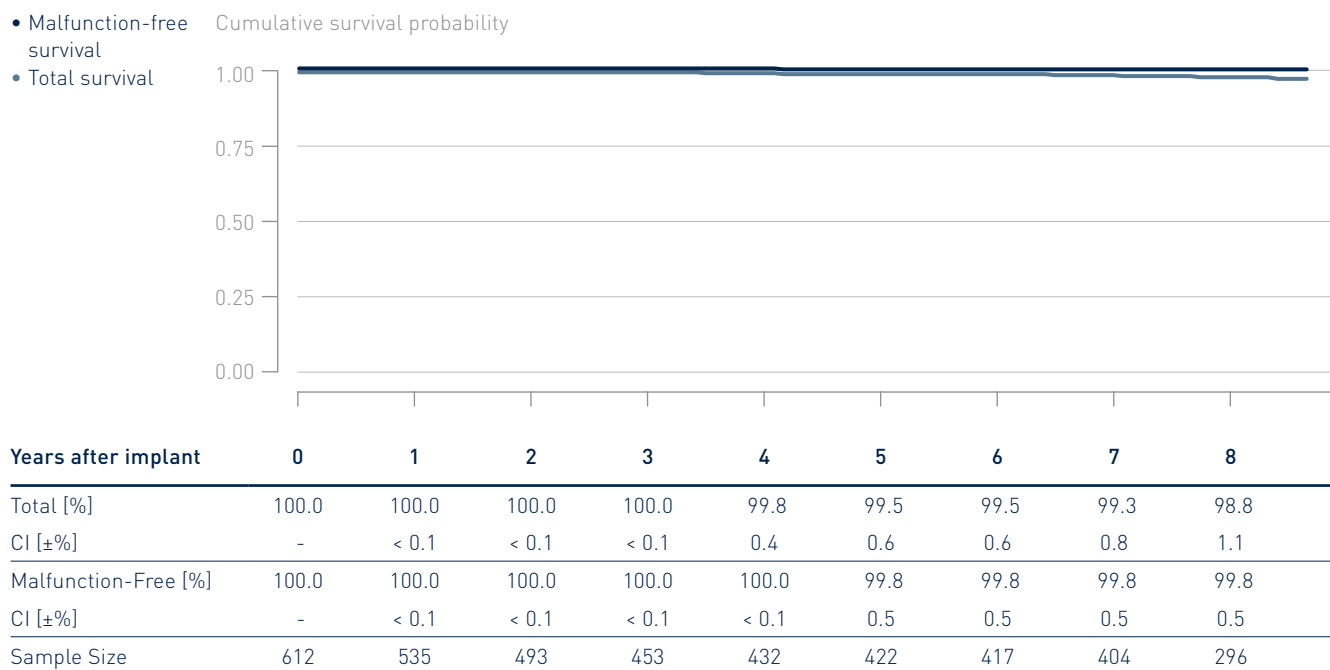


## 3.1 Single-Chamber Pacemakers

### Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, WIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	39 500
Registered U.S. Implants	612
Estimated Active U.S. Implants	381
U.S. Normal Battery Depletions	5

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	1	0.16%
Therapy Compromised	0	0.00%
Therapy Available	1	0.16%

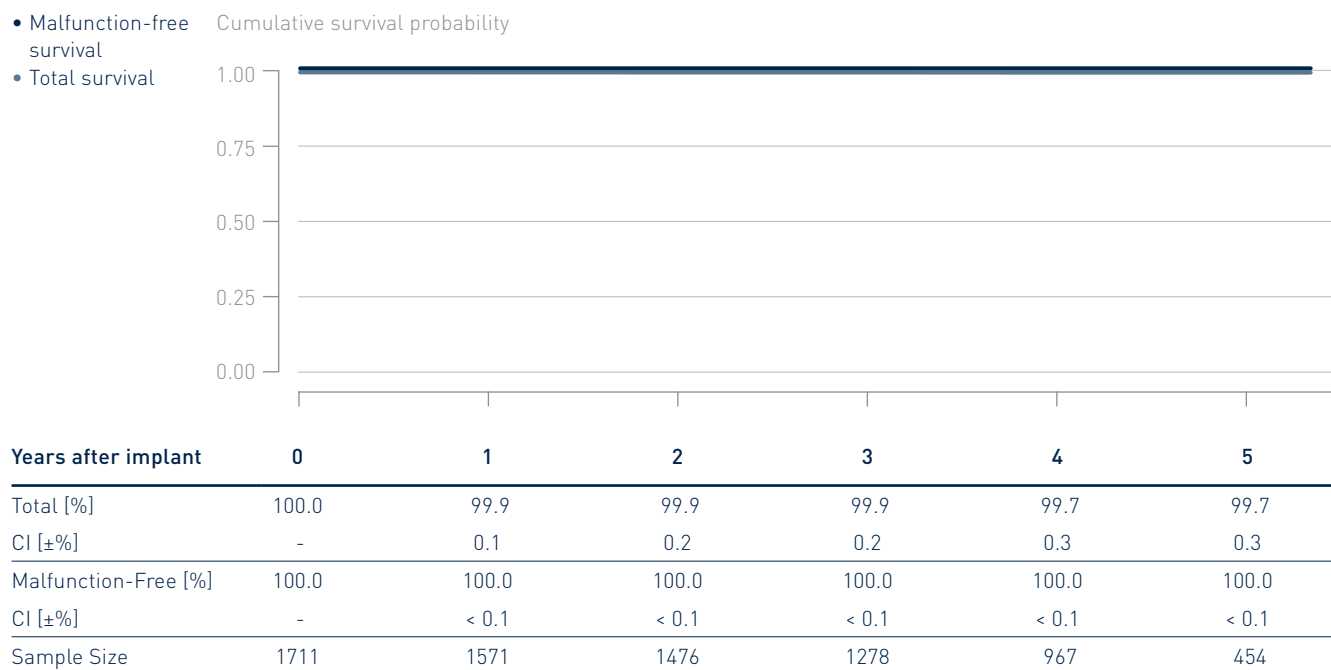


## 3.1 Single-Chamber Pacemakers

### Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, WVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18500
Registered U.S. Implants	1711
Estimated Active U.S. Implants	1310
U.S. Normal Battery Depletions	4

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

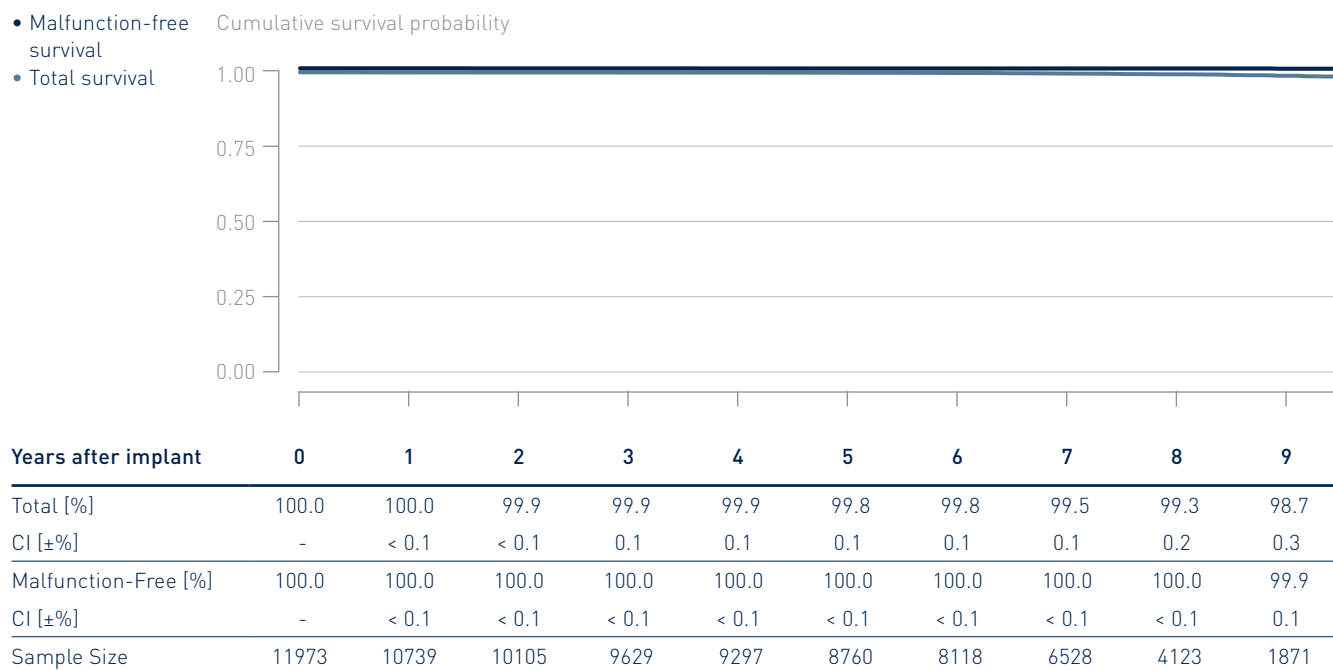


## 3.1 Single-Chamber Pacemakers

### Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, WVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	62 800
Registered U.S. Implants	11 973
Estimated Active U.S. Implants	7 440
U.S. Normal Battery Depletions	74

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	3	0.03%
Therapy Compromised	2	0.02%
Therapy Available	1	0.01%

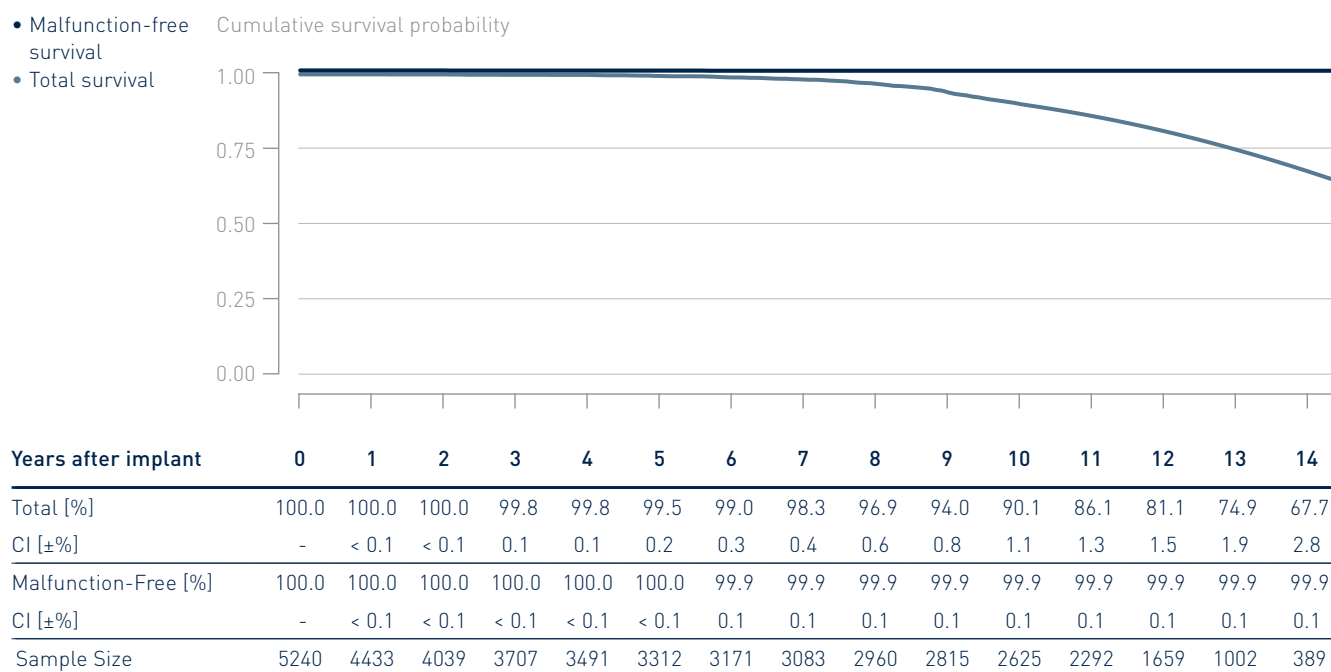


## 3.1 Single-Chamber Pacemakers

### Philos II and Talos

Product Versions _____	S, SR
NBG Codes _____	SSI, SSIR
US Market Release _____	Sep 2004
CE Market Release _____	Feb 2004 / May 2006
Worldwide Distributed Devices _____	215 000
Registered U.S. Implants _____	5 240
Estimated Active U.S. Implants _____	2 350
U.S. Normal Battery Depletions _____	399

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	2	0.04%
Therapy Compromised _____	1	0.02%
Therapy Available _____	1	0.02%



\* While Talos SR and Talos S are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products



# Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

**3.2 Dual-Chamber Pacemakers**

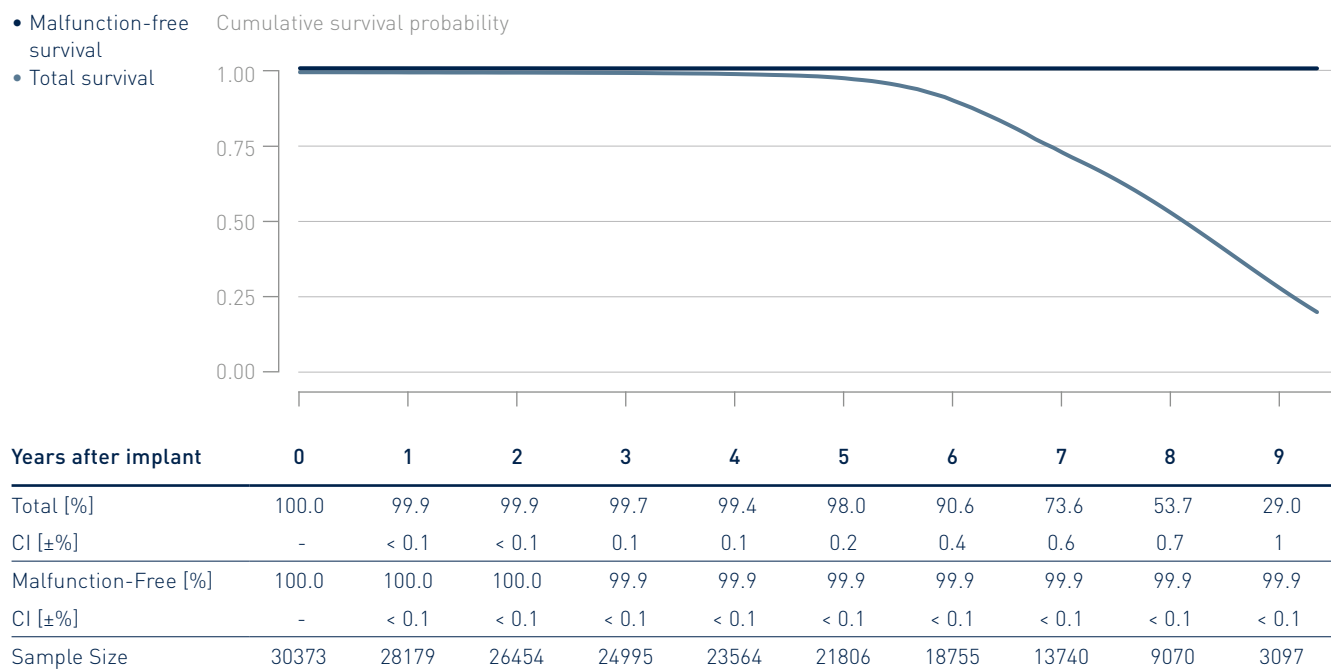
3.3 CRT Pacemakers

## 3.2 Dual-Chamber Pacemakers

### Cylos and Cylos 990

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	81 300
Registered U.S. Implants	30 373
Estimated Active U.S. Implants	7 230
U.S. Normal Battery Depletions	8 451

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	27	0.09%
Therapy Compromised	7	0.02%
Therapy Available	20	0.07%



\*While Cylos 990 DR and Cylos 990 DR-T are not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products

## 3.2 Dual-Chamber Pacemakers

### Edora 8

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	May 2017
CE Market Release _____	Jul 2016
Worldwide Distributed Devices _____	178 000
Registered U.S. Implants _____	58 642
Estimated Active U.S. Implants _____	52 600
U.S. Normal Battery Depletions _____	24

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	4	0.01%
Therapy Compromised _____	3	0.01%
Therapy Available _____	1	0.00%

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3
Total [%]	100.0	100.0	100.0	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	58642	40119	24055	8172

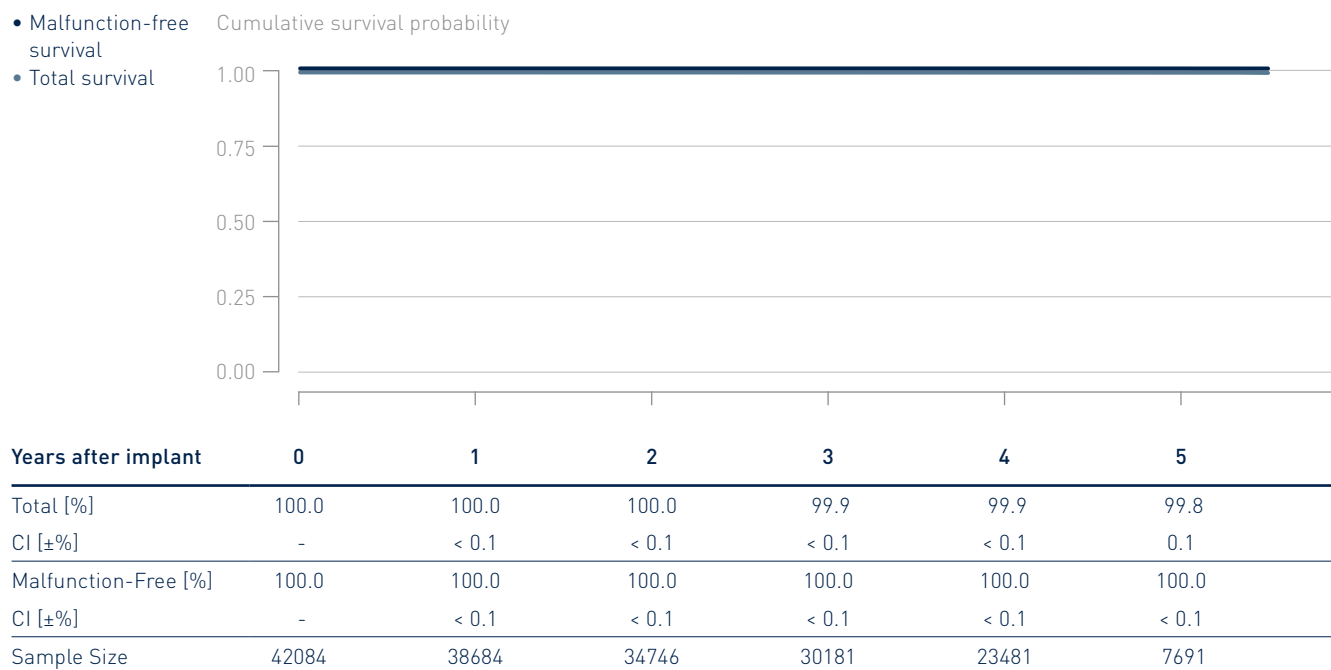


## 3.2 Dual-Chamber Pacemakers

### Eluna 8

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	97 200
Registered U.S. Implants _____	42 084
Estimated Active U.S. Implants _____	32 800
U.S. Normal Battery Depletions _____	47

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	5	0.01%
Therapy Compromised _____	0	0.00%
Therapy Available _____	5	0.01%



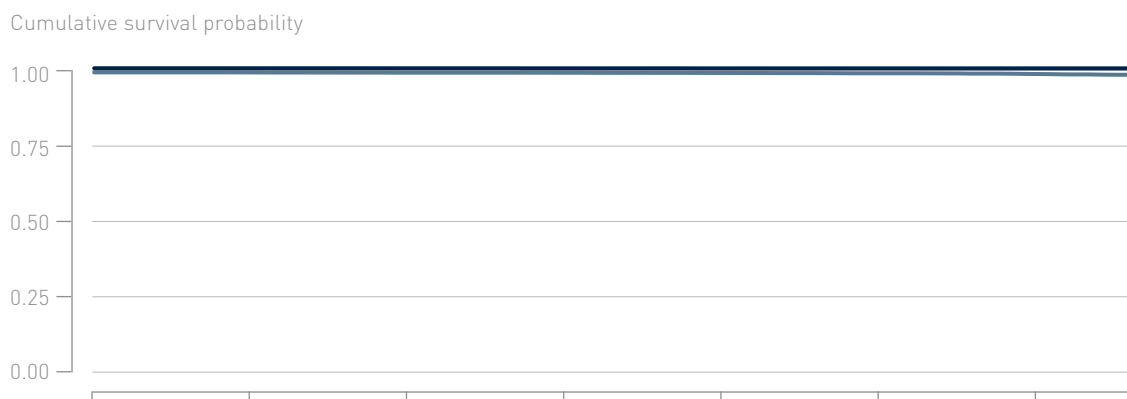
## 3.2 Dual-Chamber Pacemakers

### Entovis

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Feb 2010
CE Market Release _____	Nov 2009
Worldwide Distributed Devices _____	105 000
Registered U.S. Implants _____	12 128
Estimated Active U.S. Implants _____	8 190
U.S. Normal Battery Depletions _____	46

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	4	0.03%
Therapy Compromised _____	2	0.02%
Therapy Available _____	2	0.02%

- Malfunction-free survival
- Total survival



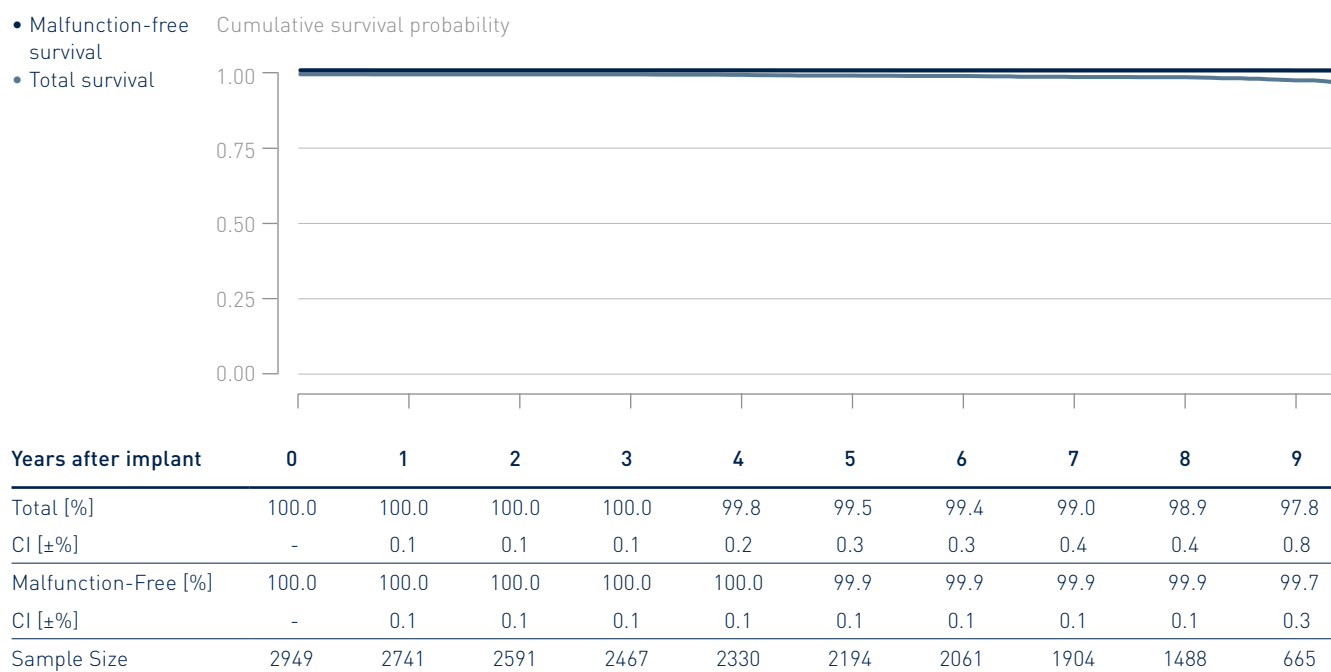
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.9	99.8	99.8	99.6
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	12128	11335	10622	9986	9371	8601	6637

## 3.2 Dual-Chamber Pacemakers

### Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	48400
Registered U.S. Implants	2949
Estimated Active U.S. Implants	1830
U.S. Normal Battery Depletions	35

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	4	0.14%
Therapy Compromised	0	0.00%
Therapy Available	4	0.14%

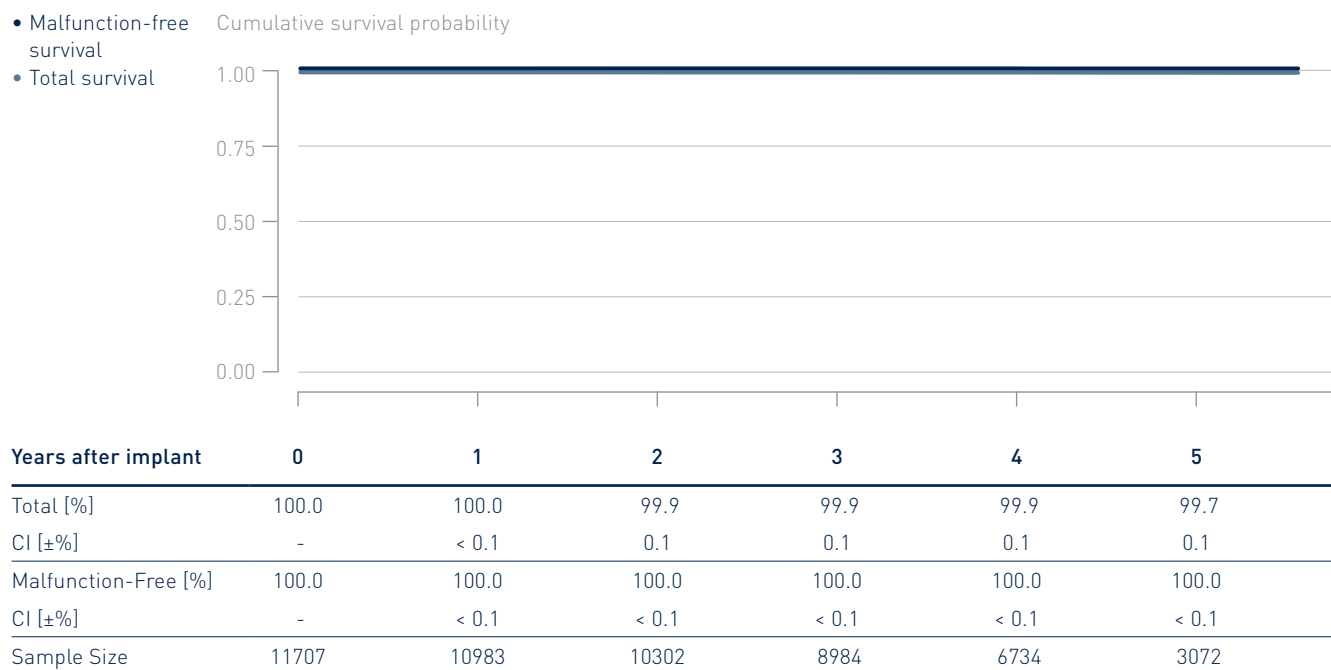


## 3.2 Dual-Chamber Pacemakers

### Etrinsa 8

Product Versions _____	DR-T
NBG Codes _____	DDDR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	76300
Registered U.S. Implants _____	11707
Estimated Active U.S. Implants _____	9110
U.S. Normal Battery Depletions _____	23

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	1	0.01%
Therapy Compromised _____	0	0.00%
Therapy Available _____	1	0.01%

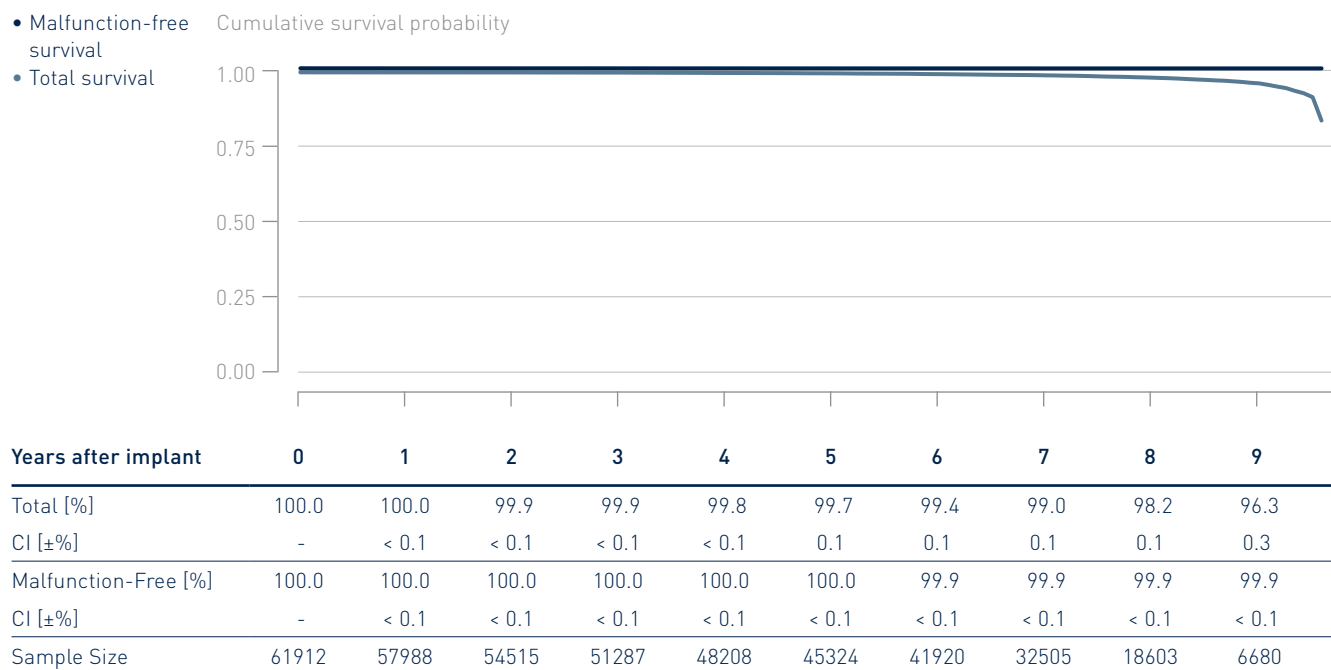


## 3.2 Dual-Chamber Pacemakers

### Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	219 000
Registered U.S. Implants	61 912
Estimated Active U.S. Implants	37 700
U.S. Normal Battery Depletions	1 017

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	30	0.05%
Therapy Compromised	11	0.02%
Therapy Available	19	0.03%

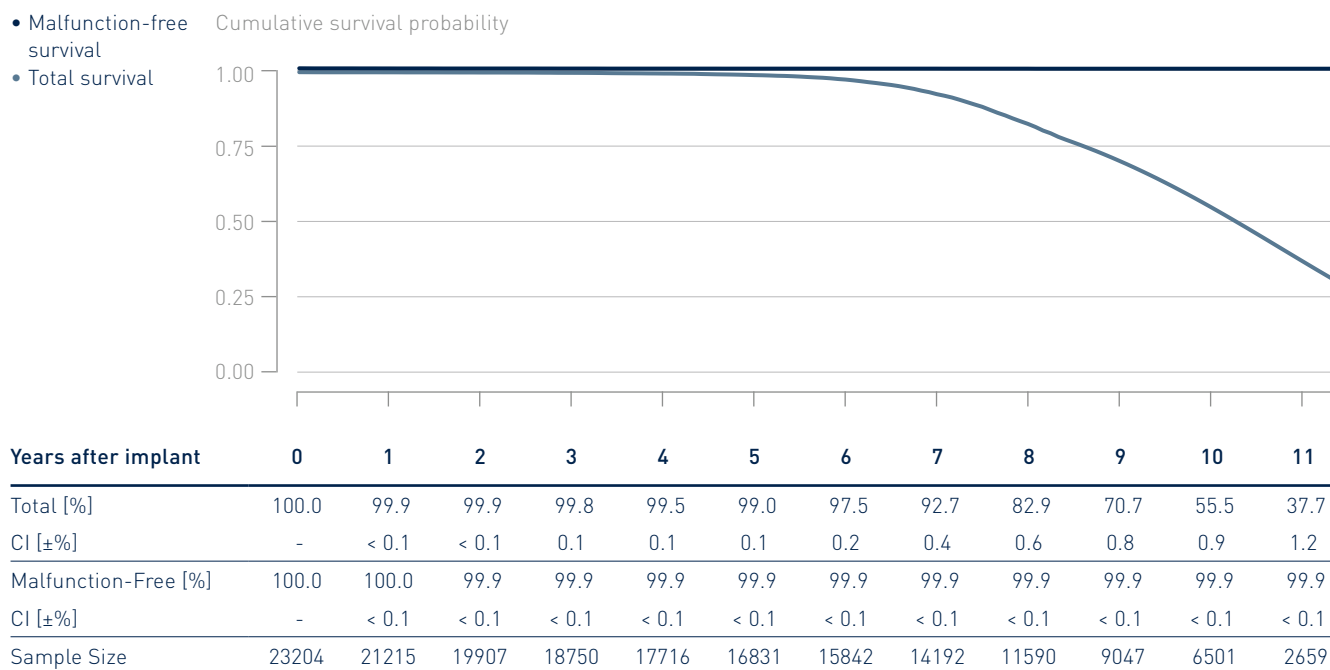


## 3.2 Dual-Chamber Pacemakers

### Philos II and Talos

Product Versions	D, DR, DR-T (Philos II only), SLR
NBG Codes	DDD, DDDR, VDDR
US Market Release	Sep 2004
CE Market Release	Feb 2004 / May 2006
Worldwide Distributed Devices	372 000
Registered U.S. Implants	23 204
Estimated Active U.S. Implants	6 860
U.S. Normal Battery Depletions	4 747

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	21	0.09%
Therapy Compromised	0	0.00%
Therapy Available	21	0.09%





# Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

**3.3 CRT Pacemakers**

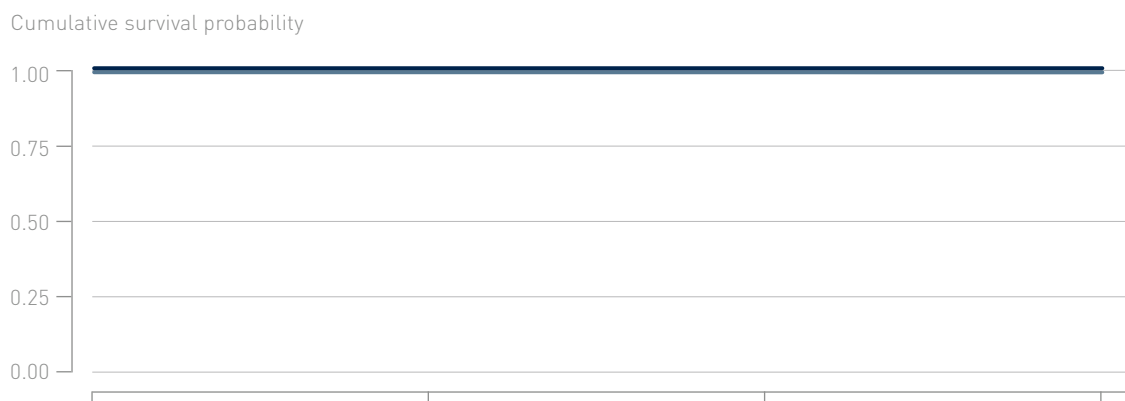
### 3.3 CRT Pacemakers

#### Edora 8

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	DDDRV
US Market Release _____	Jun 2017
CE Market Release _____	Mar 2017
Worldwide Distributed Devices _____	13 600
Registered U.S. Implants _____	4 836
Estimated Active U.S. Implants _____	3 990
U.S. Normal Battery Depletions _____	4

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	0	0.00%
Therapy Compromised _____	0	0.00%
Therapy Available _____	0	0.00%

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.7
CI [±%]	-	< 0.1	0.1	0.3
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	4836	2993	1489	224

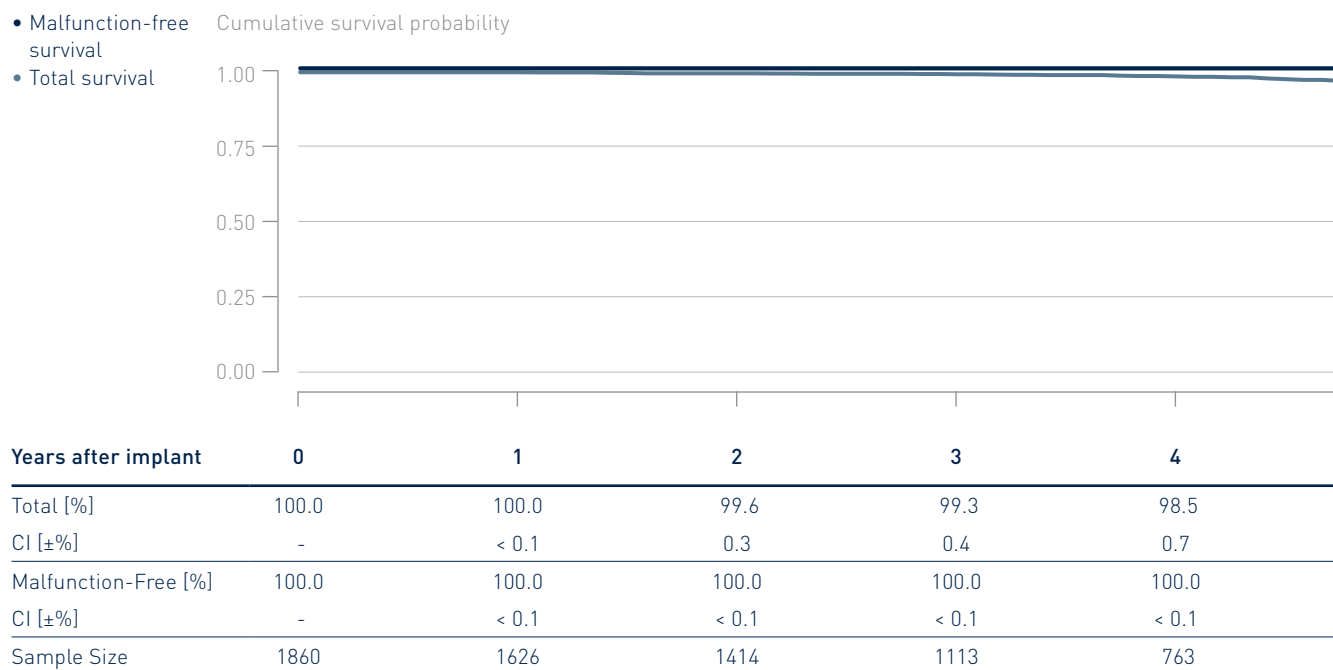


## 3.3 CRT Pacemakers

### Etrinsa 8

Product Versions	HF-T
NBG Codes	DDDRV
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	8 670
Registered U.S. Implants	1 860
Estimated Active U.S. Implants	1 120
U.S. Normal Battery Depletions	28

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

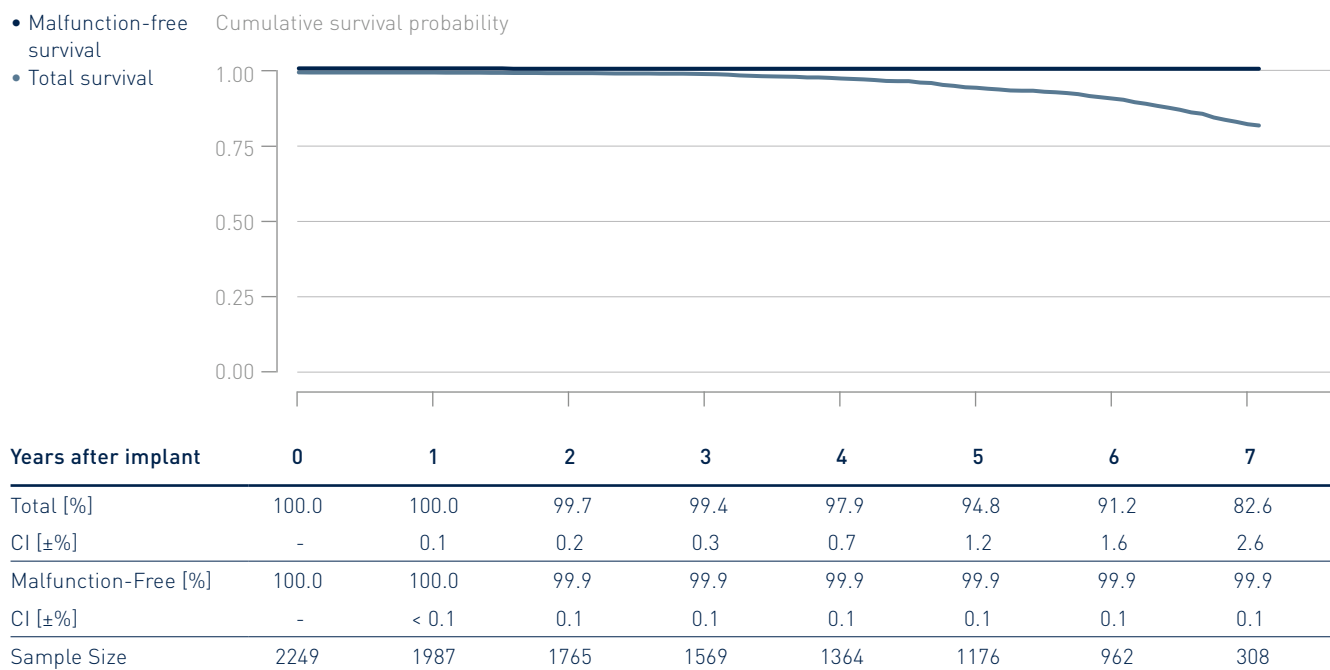


### 3.3 CRT Pacemakers

## Evia

Product Versions	HF, HF-T
NBG Codes	DDDRV
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	8880
Registered U.S. Implants	2249
Estimated Active U.S. Implants	889
U.S. Normal Battery Depletions	177

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	1	0.04%
Therapy Compromised	0	0.00%
Therapy Available	1	0.04%

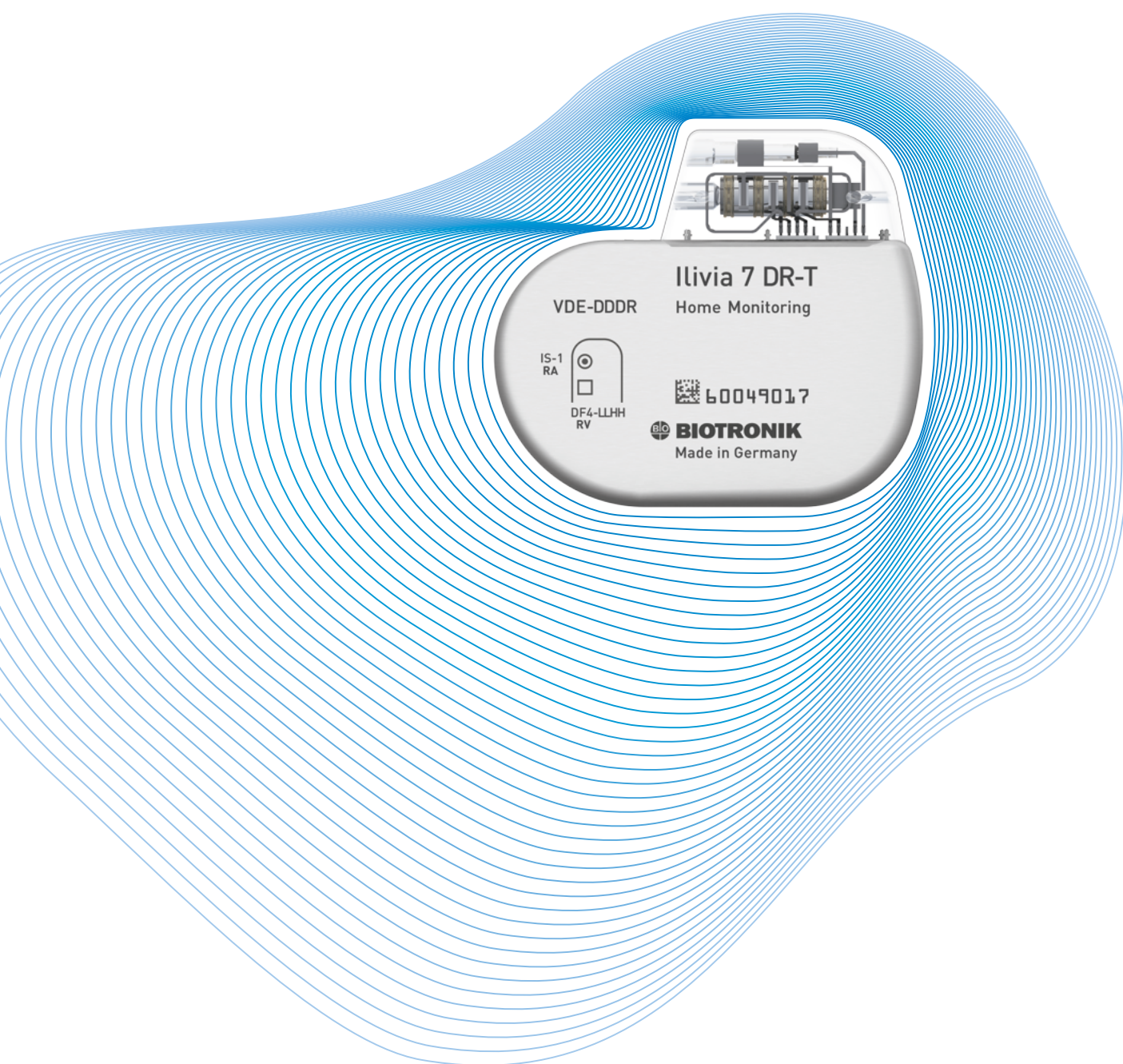


# Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs

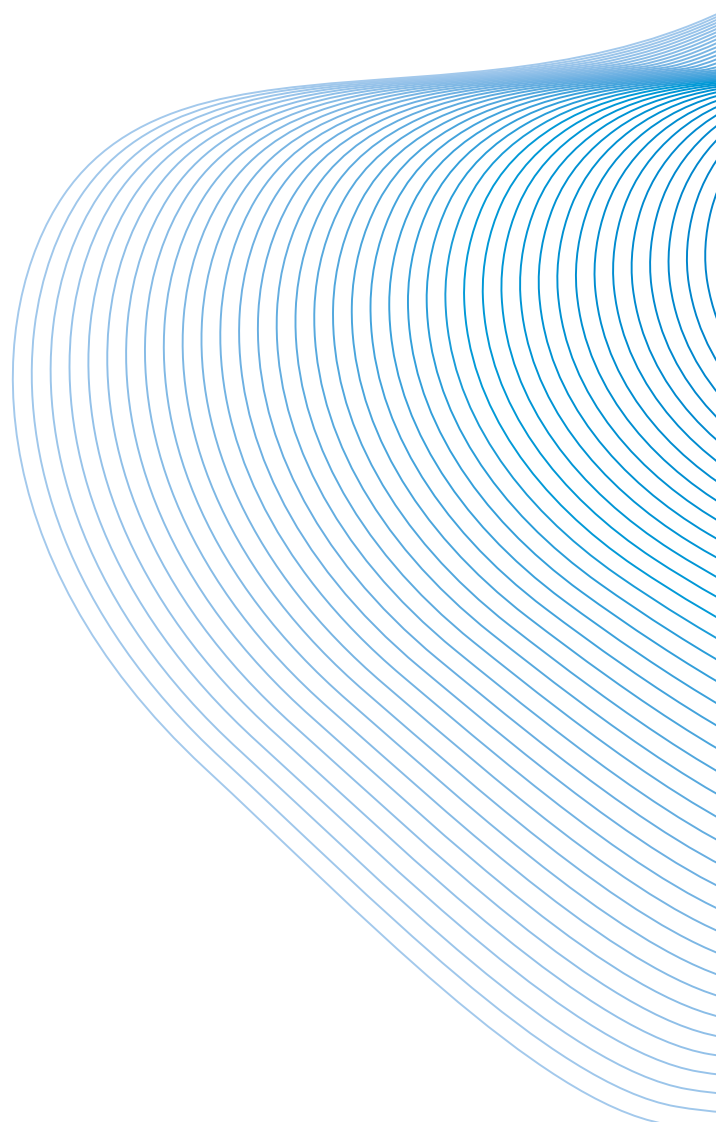


# Performance of BIOTRONIK ICDs

## 4.1 Single-Chamber ICDs

## 4.2 Dual-Chamber ICDs

## 4.3 CRT ICDs

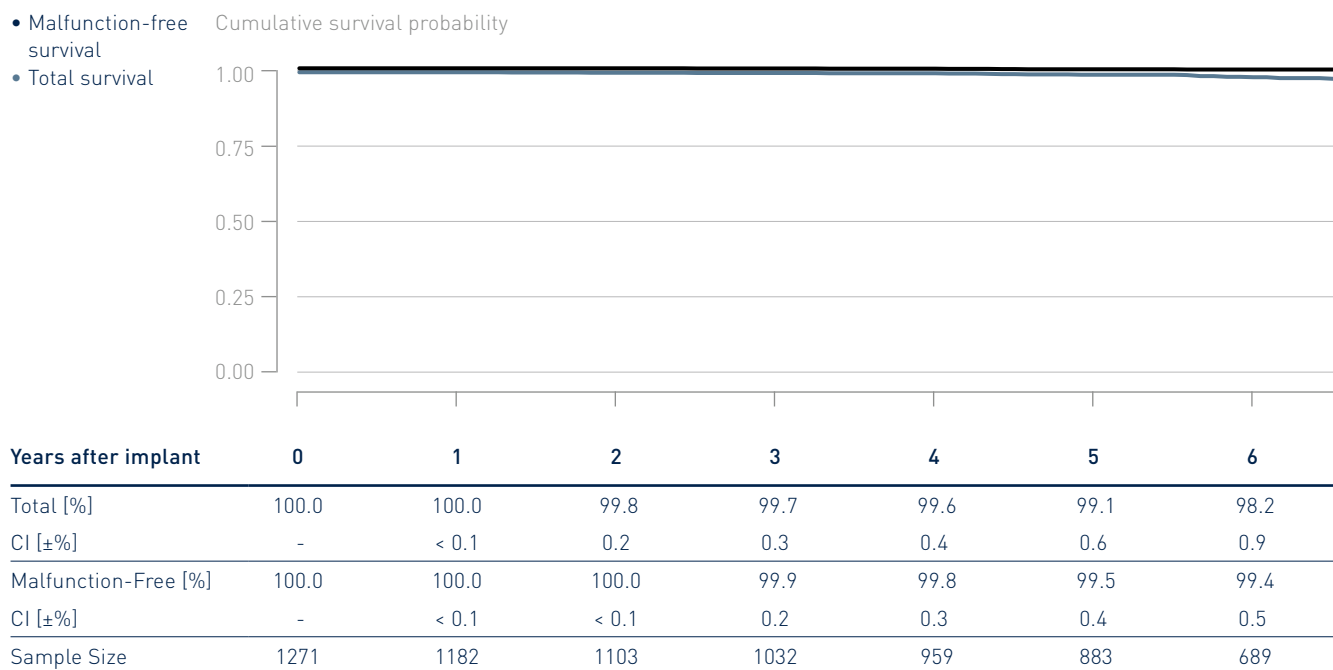


## 4.1 Single-Chamber ICDs

### Ilesto 7

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2460
Registered U.S. Implants _____	1271
Estimated Active U.S. Implants _____	832
U.S. Normal Battery Depletions _____	14

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	7	0.55%
Therapy Compromised _____	4	0.31%
Therapy Available _____	3	0.24%



\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

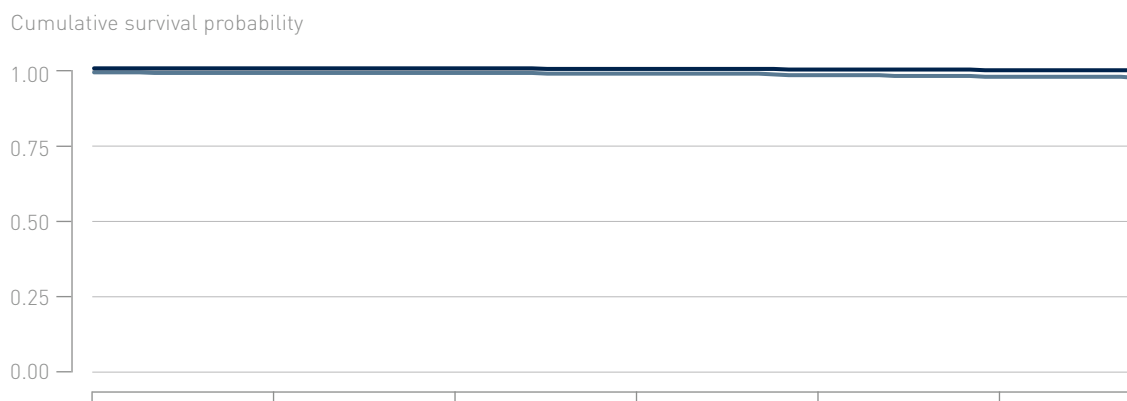
## 4.1 Single-Chamber ICDs

### Ilesto 7 DF4

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2390
Registered U.S. Implants _____	466
Estimated Active U.S. Implants _____	291
U.S. Normal Battery Depletions _____	4

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	3	0.64%
Therapy Compromised _____	2	0.43%
Therapy Available _____	1	0.21%

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.8	99.5	98.9	98.3
CI [±%]	-	0.4	0.4	0.7	1	1.3
Malfunction-Free [%]	100.0	100.0	100.0	99.7	99.4	99.1
CI [±%]	-	< 0.1	< 0.1	0.5	0.8	1
Sample Size	466	429	392	365	341	305

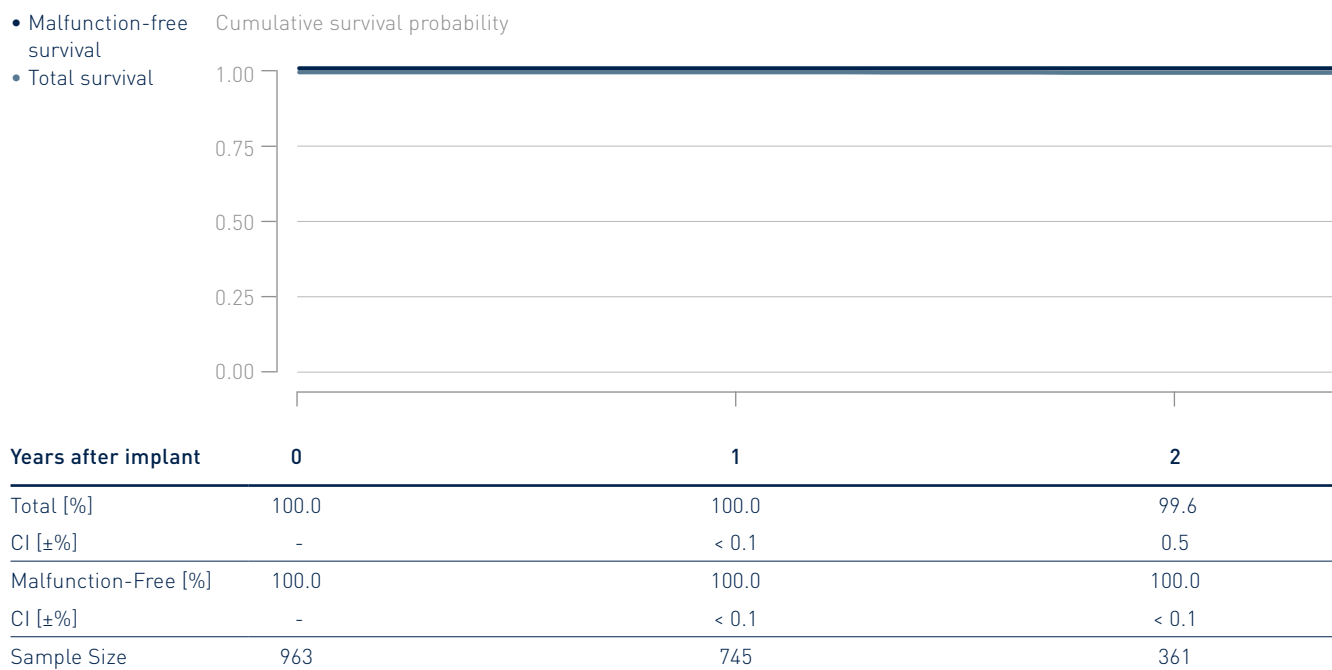
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.1 Single-Chamber ICDs

### Ilivia 7

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	May 2017
Worldwide Distributed Devices _____	2380
Registered U.S. Implants _____	963
Estimated Active U.S. Implants _____	840
U.S. Normal Battery Depletions _____	2

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	0	0.00%
Therapy Compromised _____	0	0.00%
Therapy Available _____	0	0.00%



\* A subset of devices from this product family is subject to the advisory BIO-LQC.  
Refer to the chapter "Advisories" for details.

## 4.1 Single-Chamber ICDs

### Ilivia 7 DF4

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Aug 2017
CE Market Release _____	Mar 2017
Worldwide Distributed Devices _____	4 230
Registered U.S. Implants _____	878
Estimated Active U.S. Implants _____	721
U.S. Normal Battery Depletions _____	1

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	2	0.23%
Therapy Compromised _____	0	0.00%
Therapy Available _____	2	0.23%

• Malfunction-free survival

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.7	99.6
CI [±%]	-	0.2	0.4	0.5
Malfunction-Free [%]	100.0	100.0	99.9	99.7
CI [±%]	-	< 0.1	0.3	0.4
Sample Size	878	808	668	245

\* A subset of devices from this product family is subject to the advisory BIO-LQC.  
Refer to the chapter "Advisories" for details.



## 4.1 Single-Chamber ICDs

### Itrevia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1280
Registered U.S. Implants	618
Estimated Active U.S. Implants	442
U.S. Normal Battery Depletions	6

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	3	0.49%
Therapy Compromised	3	0.49%
Therapy Available	0	0.00%

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.8	99.6	98.9
CI [±%]	-	< 0.1	0.3	0.5	1
Malfunction-Free [%]	100.0	100.0	100.0	99.8	99.5
CI [±%]	-	< 0.1	< 0.1	0.4	0.7
Sample Size	618	570	534	486	348

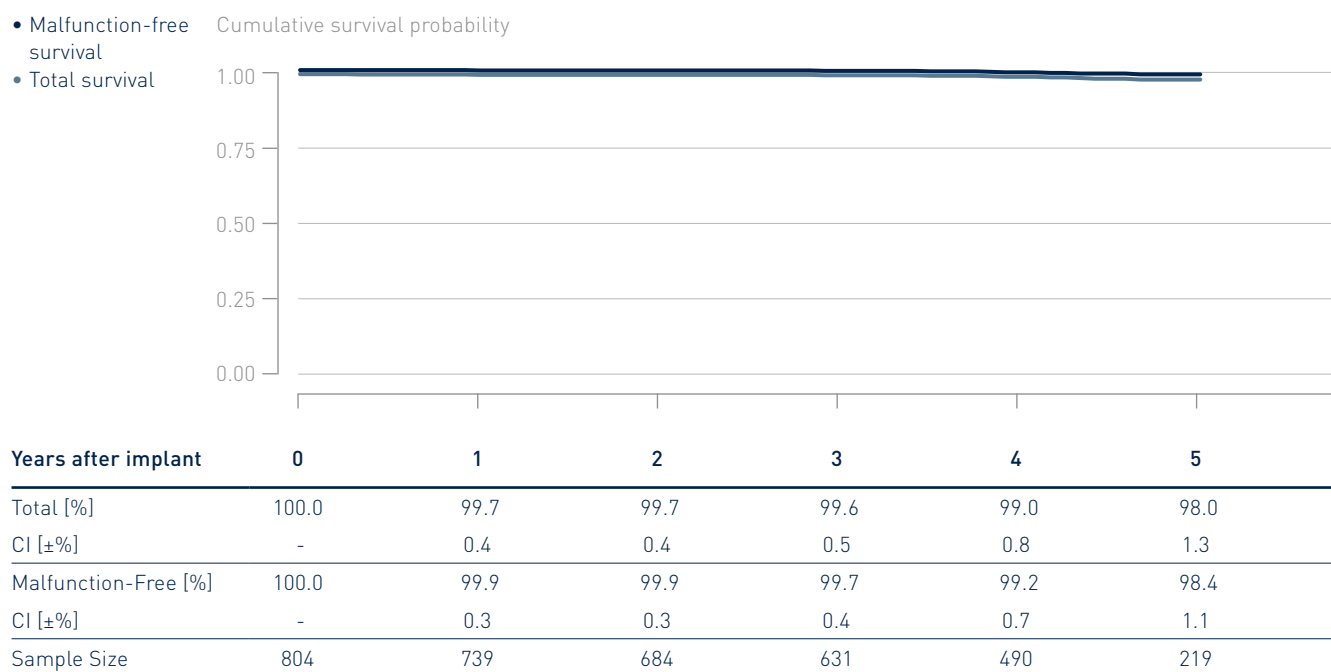
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.1 Single-Chamber ICDs

### Itrevia 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 420
Registered U.S. Implants	804
Estimated Active U.S. Implants	586
U.S. Normal Battery Depletions	4

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	10	1.24%
Therapy Compromised	2	0.25%
Therapy Available	8	1.00%



\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

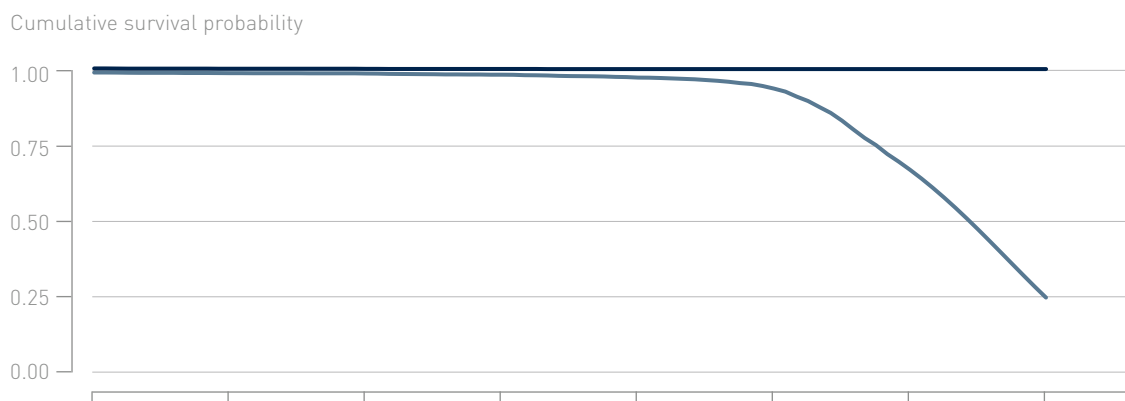
## 4.1 Single-Chamber ICDs

### Lumax 340

Product Versions	VR, VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	27 100
Registered U.S. Implants	3 985
Estimated Active U.S. Implants	896
U.S. Normal Battery Depletions	930

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	6	0.15%
Therapy Compromised	4	0.10%
Therapy Available	2	0.05%

- Malfunction-free survival
- Total survival



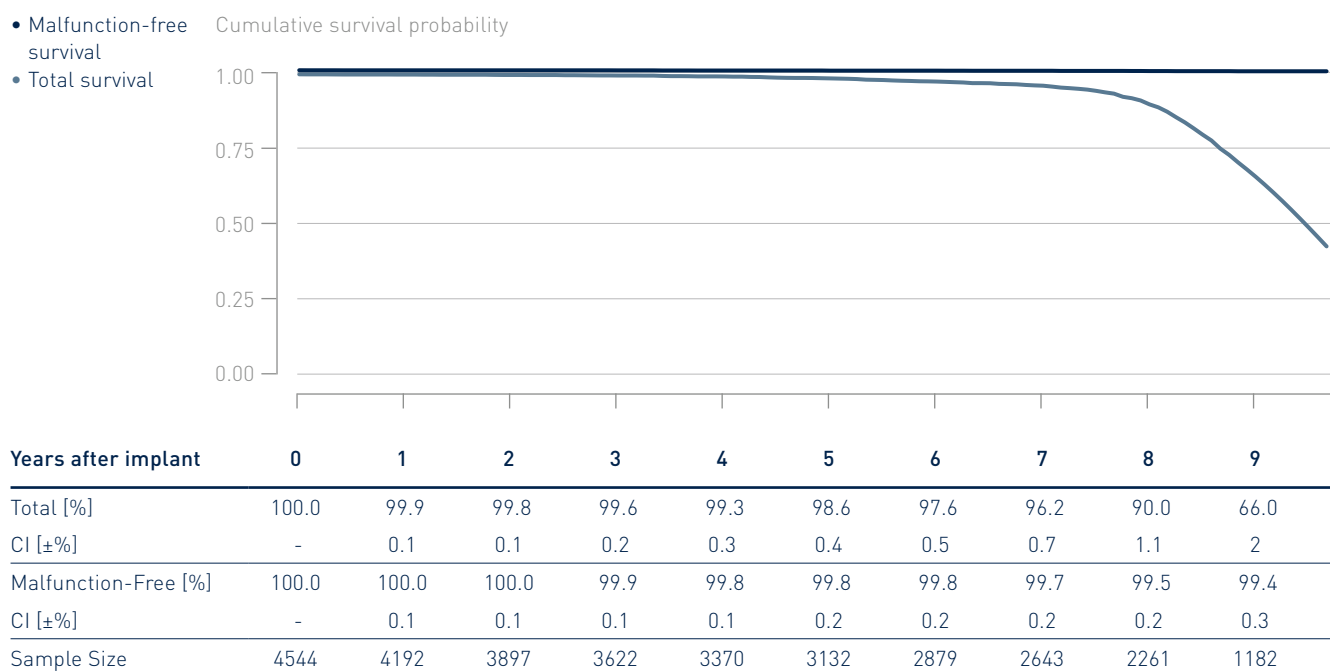
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.7	99.3	98.3	94.7	67.9	25.7
CI [±%]	-	0.1	0.2	0.3	0.4	0.8	1.9	4.2
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3985	3616	3393	3155	2908	2550	1506	276

## 4.1 Single-Chamber ICDs

### Lumax 540

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20 000
Registered U.S. Implants	4 544
Estimated Active U.S. Implants	1 460
U.S. Normal Battery Depletions	852

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	16	0.35%
Therapy Compromised	12	0.26%
Therapy Available	4	0.09%

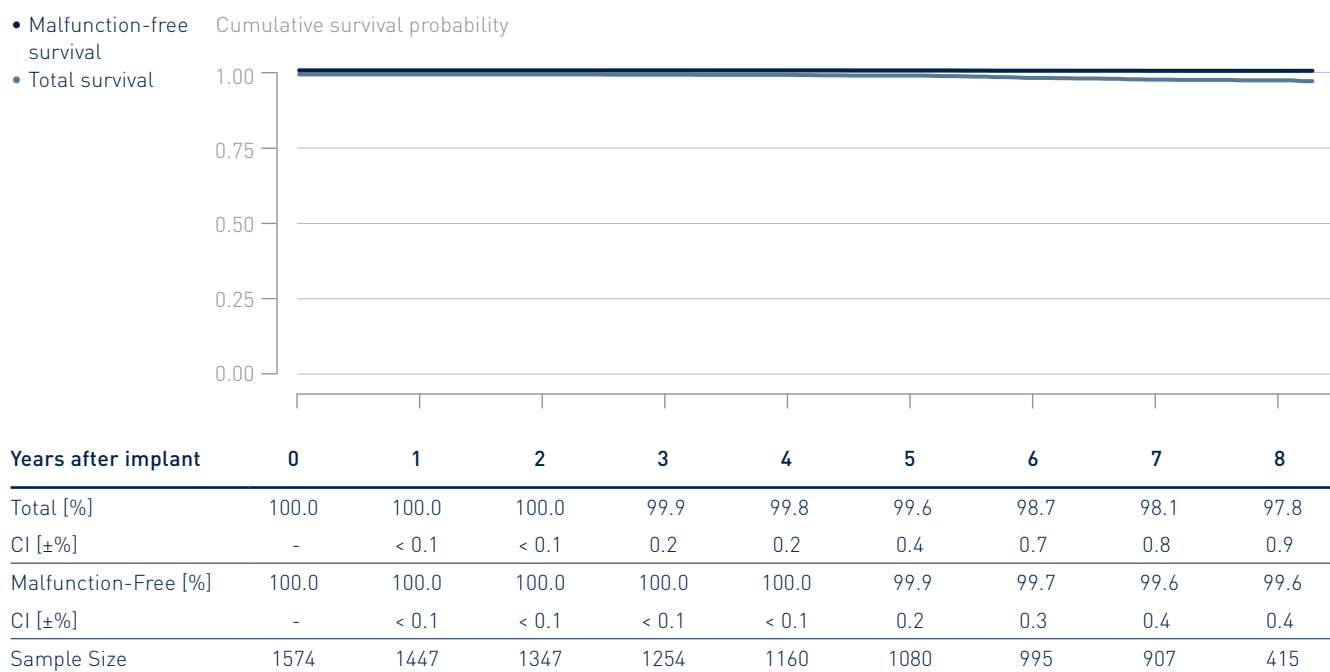


## 4.1 Single-Chamber ICDs

### Lumax 740

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	4810
Registered U.S. Implants	1574
Estimated Active U.S. Implants	892
U.S. Normal Battery Depletions	21

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	4	0.25%
Therapy Compromised	2	0.13%
Therapy Available	2	0.13%

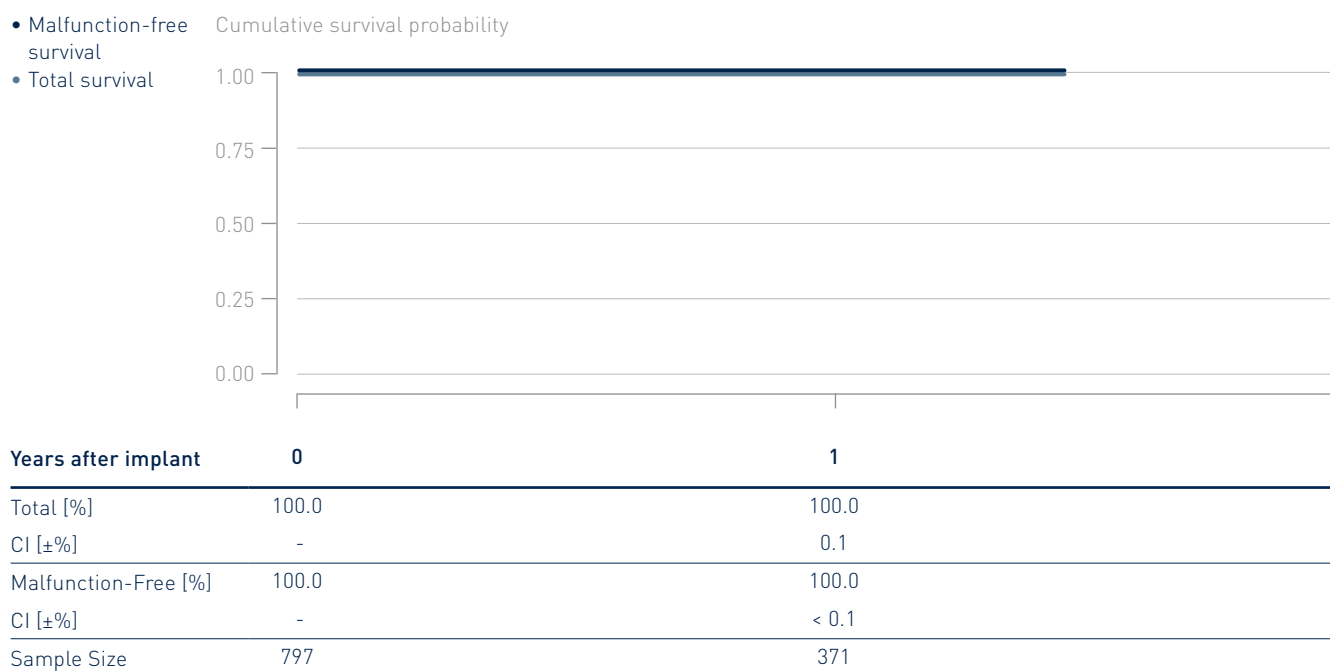


## 4.1 Single-Chamber ICDs

### Rivacor 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	2980
Registered U.S. Implants	797
Estimated Active U.S. Implants	752
U.S. Normal Battery Depletions	0

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

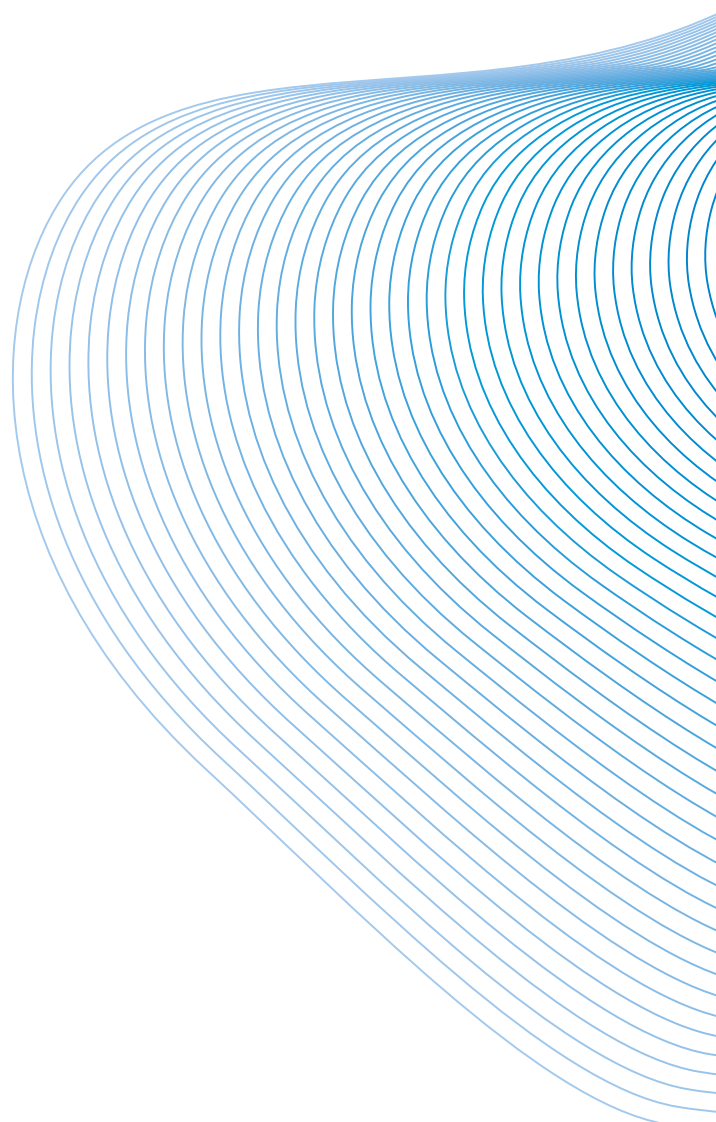


# Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

**4.2 Dual-Chamber ICDs**

4.3 CRT ICDs



## 4.2 Dual-Chamber ICDs

### Acticor 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	9 750
Registered U.S. Implants	6 783
Estimated Active U.S. Implants	6 410
U.S. Normal Battery Depletions	1

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

- Malfunction-free survival

- Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	-	< 0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	-	< 0.1
Sample Size	6783	2920

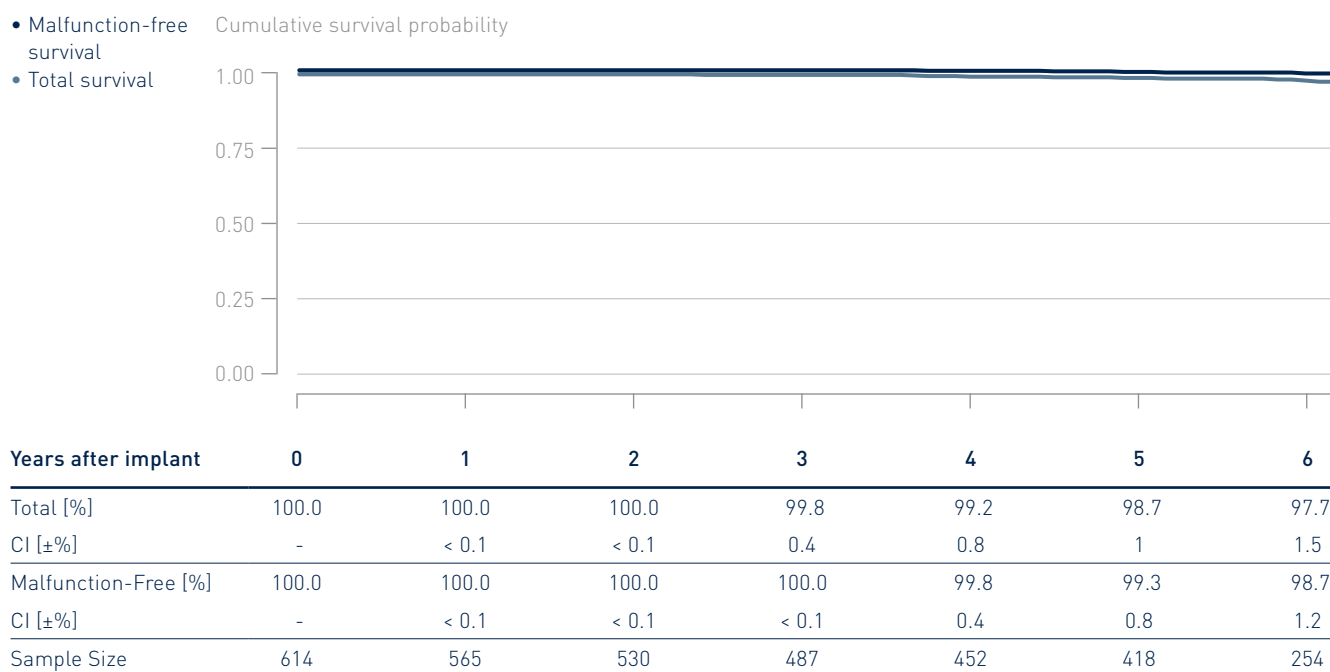


## 4.2 Dual-Chamber ICDs

### Iforia 7

Product Versions	DR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2000
Registered U.S. Implants	614
Estimated Active U.S. Implants	391
U.S. Normal Battery Depletions	7

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	6	0.98%
Therapy Compromised	2	0.33%
Therapy Available	4	0.65%



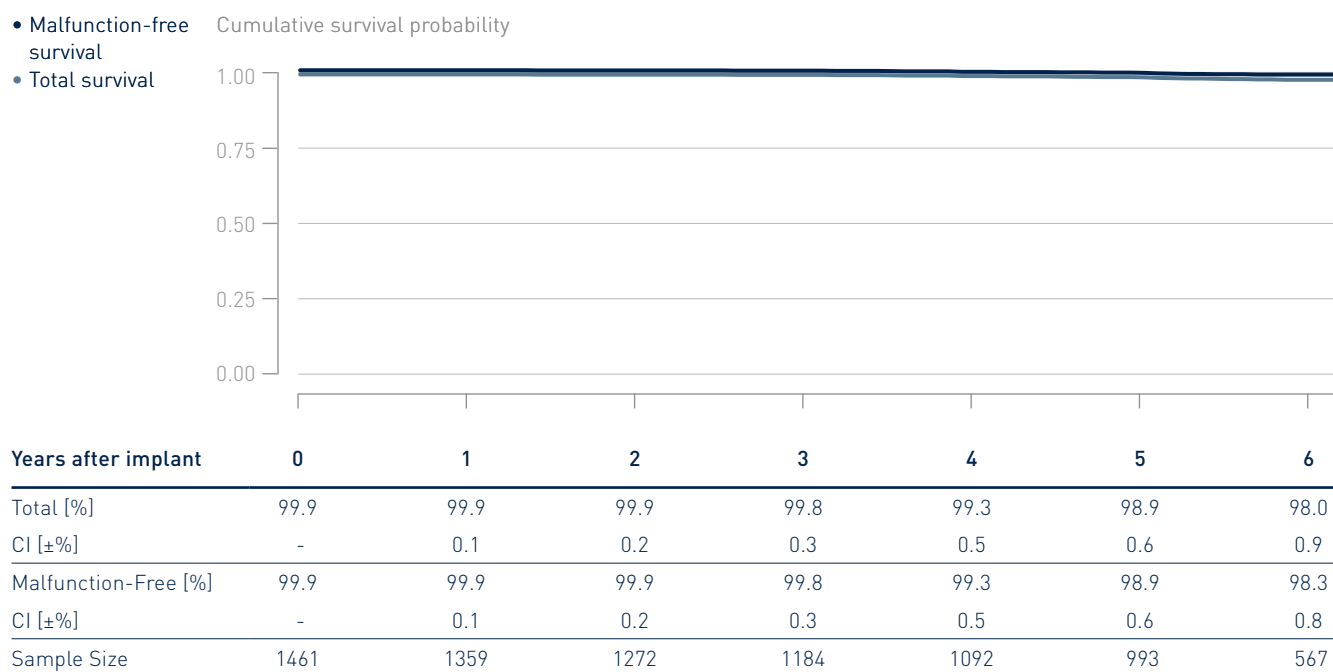
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Iforia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	4 780
Registered U.S. Implants	1 461
Estimated Active U.S. Implants	943
U.S. Normal Battery Depletions	8

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	23	1.57%
Therapy Compromised	12	0.82%
Therapy Available	11	0.75%



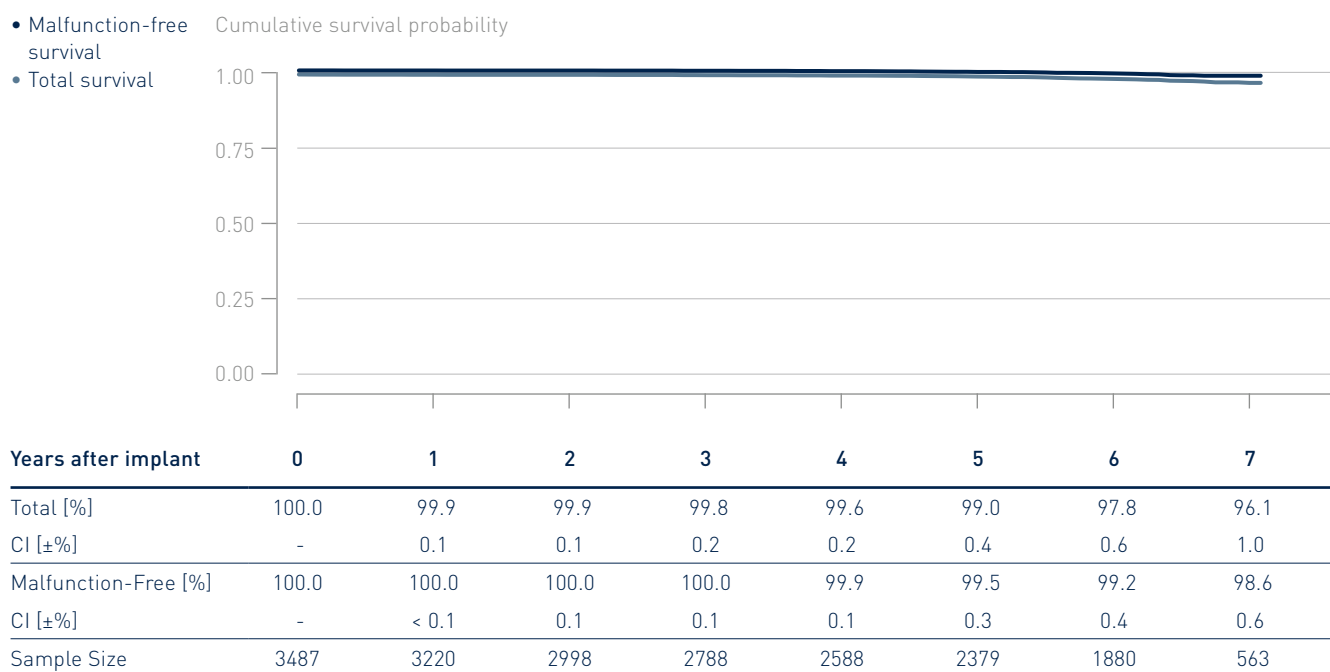
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Ilesto 7

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	5 110
Registered U.S. Implants _____	3 487
Estimated Active U.S. Implants _____	2 140
U.S. Normal Battery Depletions _____	65

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	29	0.83%
Therapy Compromised _____	18	0.52%
Therapy Available _____	11	0.32%



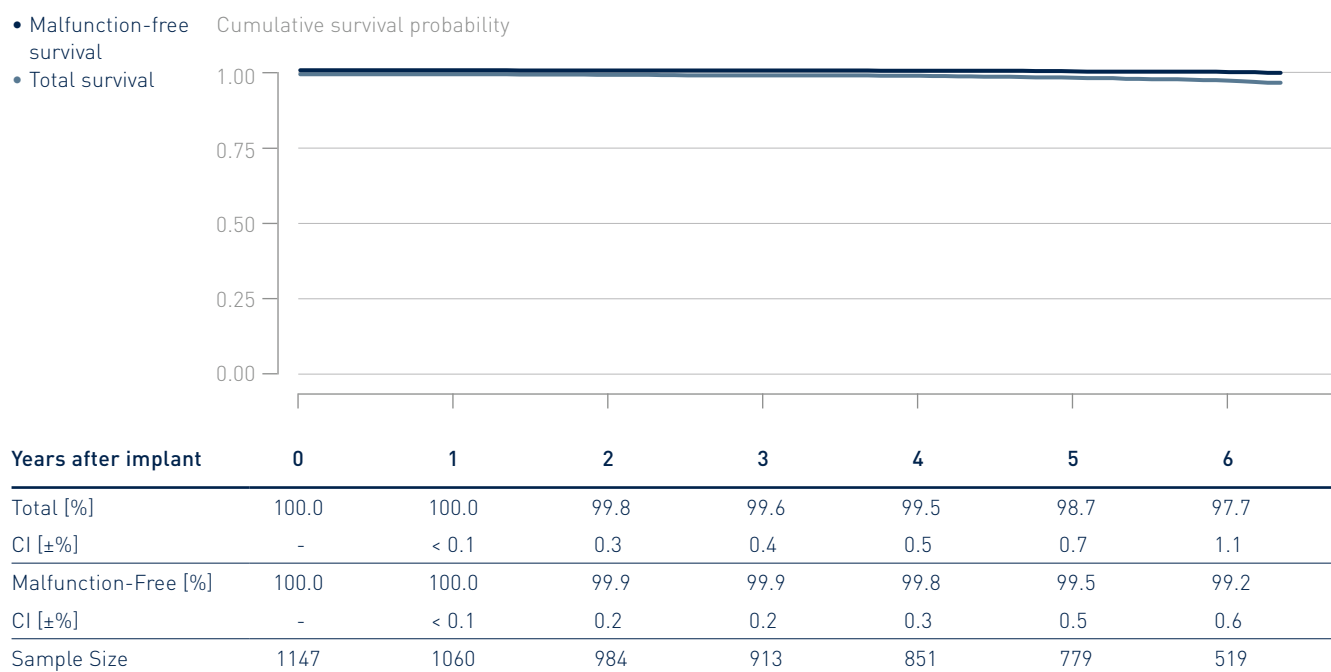
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Ilesto 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Jul 2014
CE Market Release _____	Jul 2013
Worldwide Distributed Devices _____	3730
Registered U.S. Implants _____	1147
Estimated Active U.S. Implants _____	744
U.S. Normal Battery Depletions _____	15

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	7	0.61%
Therapy Compromised _____	3	0.26%
Therapy Available _____	4	0.35%



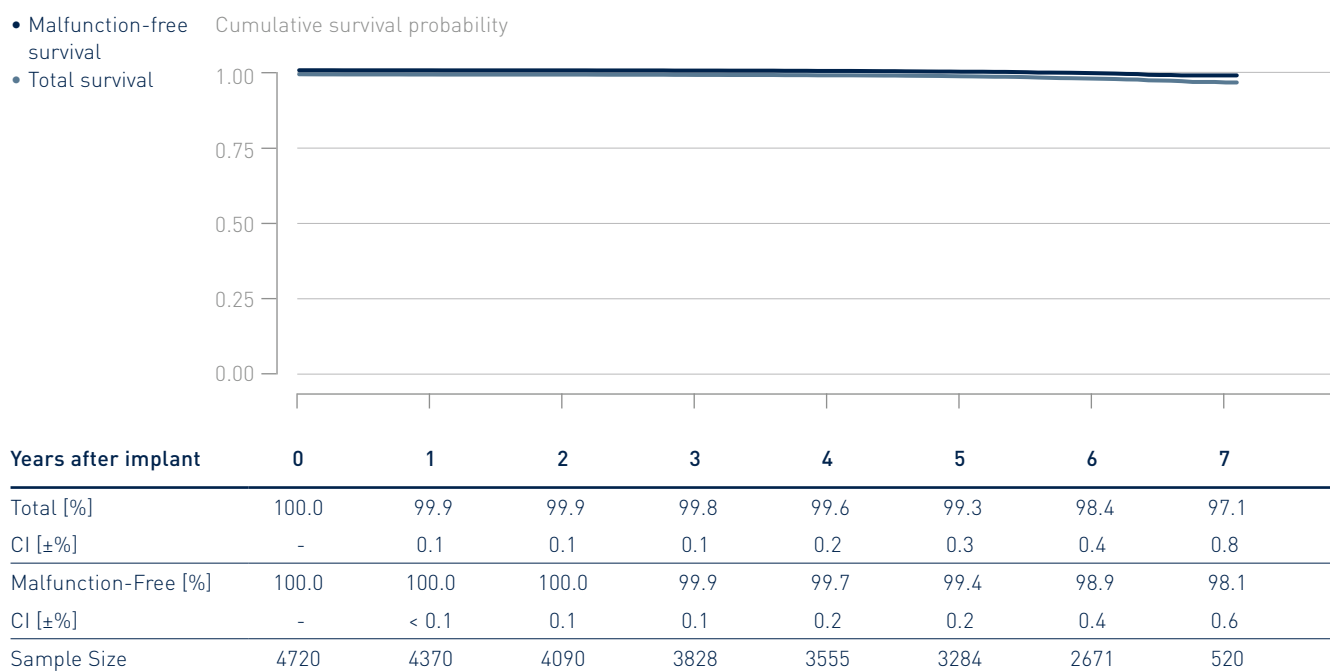
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Ilesto 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	3 030
U.S. Normal Battery Depletions	39

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	54	1.14%
Therapy Compromised	26	0.55%
Therapy Available	28	0.59%



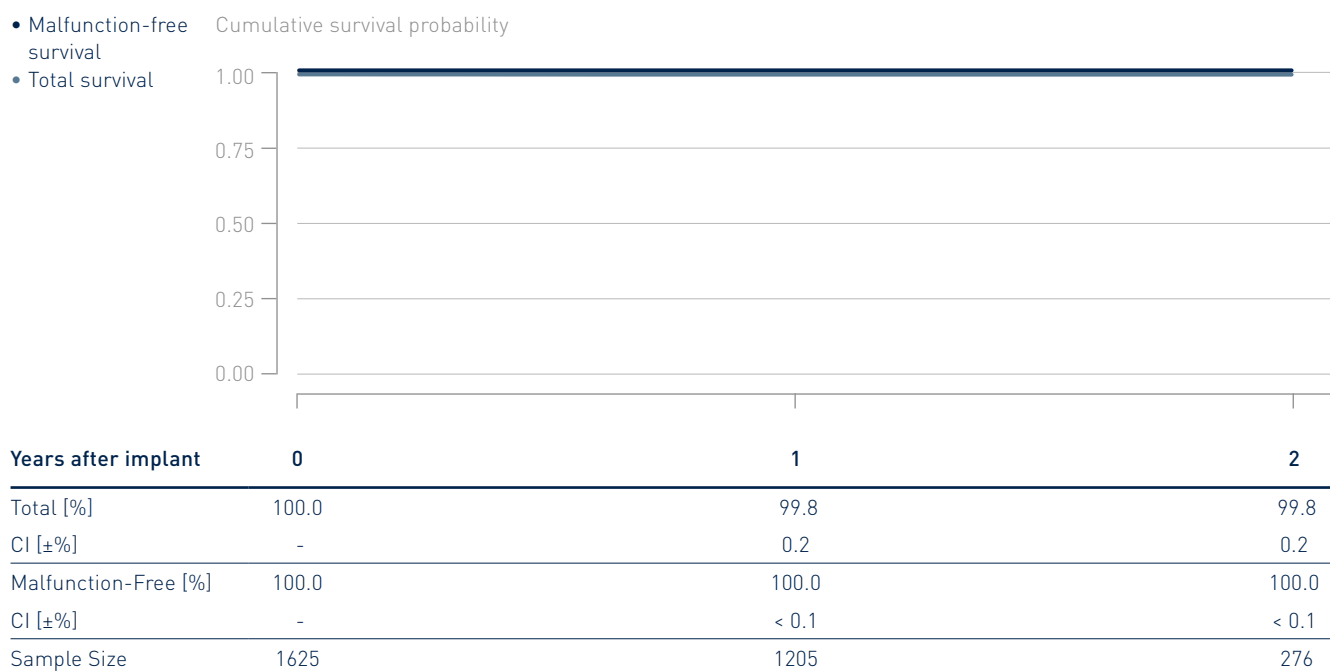
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Ilivia 7

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	May 2017
Worldwide Distributed Devices	3 170
Registered U.S. Implants	1 625
Estimated Active U.S. Implants	1 460
U.S. Normal Battery Depletions	3

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



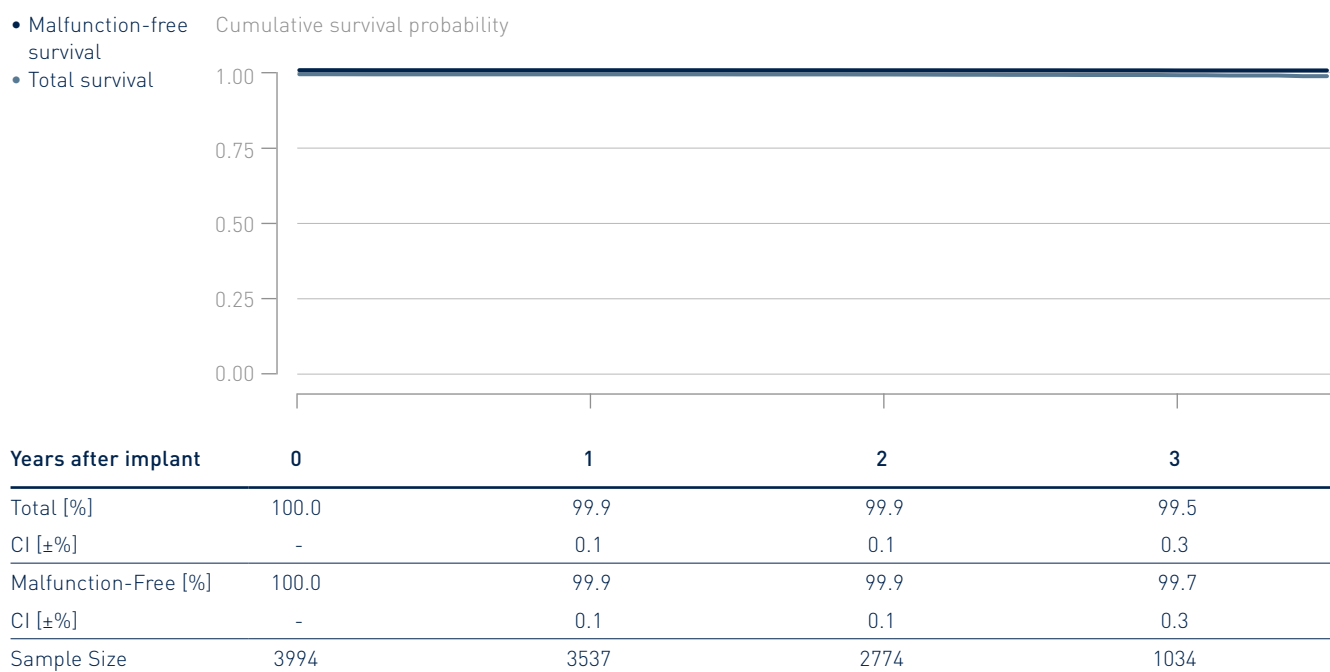
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Ilivia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Aug 2016
Worldwide Distributed Devices _____	8 540
Registered U.S. Implants _____	3 994
Estimated Active U.S. Implants _____	3 320
U.S. Normal Battery Depletions _____	5

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	10	0.25%
Therapy Compromised _____	6	0.15%
Therapy Available _____	4	0.10%



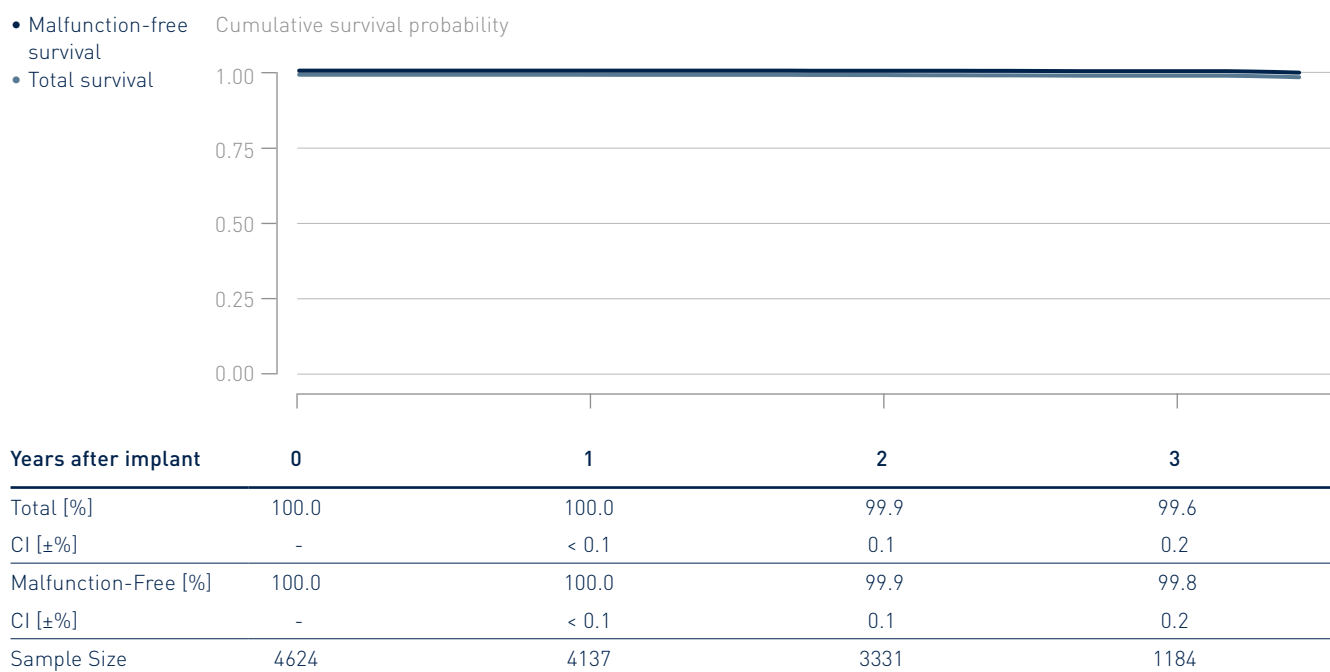
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Intica 7 DX

Product Versions	VR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 840
Registered U.S. Implants	4 624
Estimated Active U.S. Implants	3 830
U.S. Normal Battery Depletions	8

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	10	0.22%
Therapy Compromised	1	0.02%
Therapy Available	9	0.19%



\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

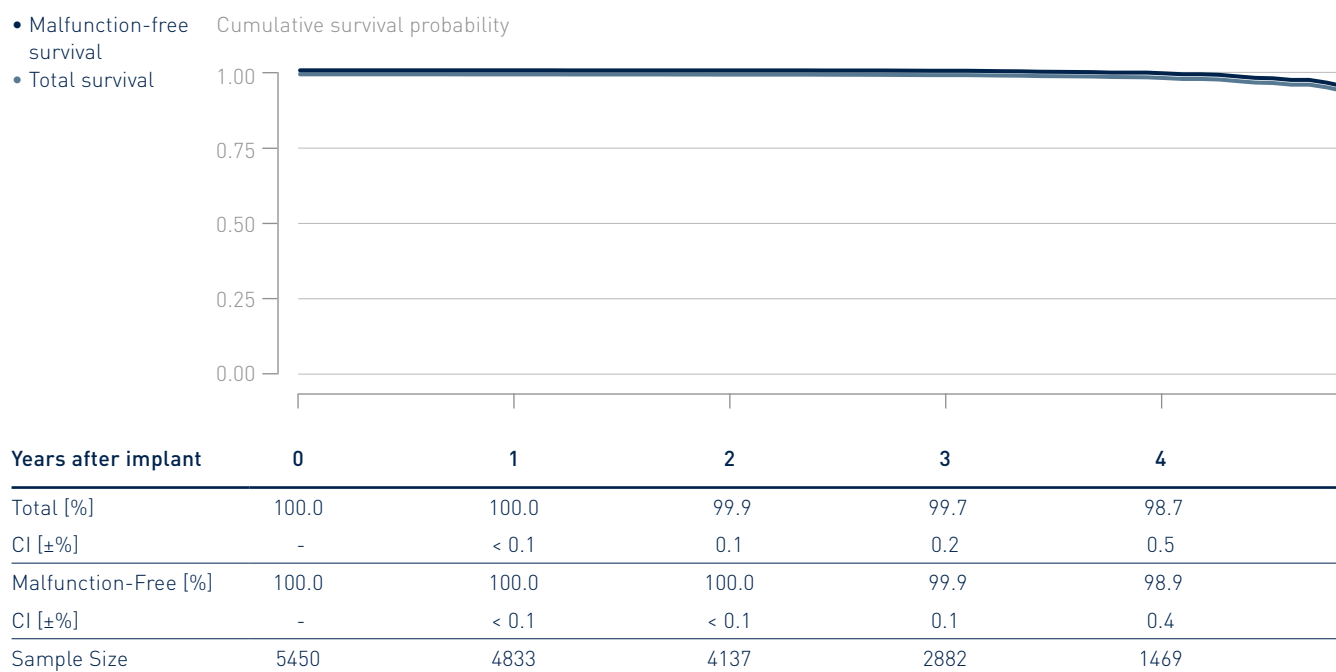


## 4.2 Dual-Chamber ICDs

### Inventra 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	45
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5790
Registered U.S. Implants	5450
Estimated Active U.S. Implants	4210
U.S. Normal Battery Depletions	13

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	56	1.03%
Therapy Compromised	22	0.40%
Therapy Available	34	0.62%



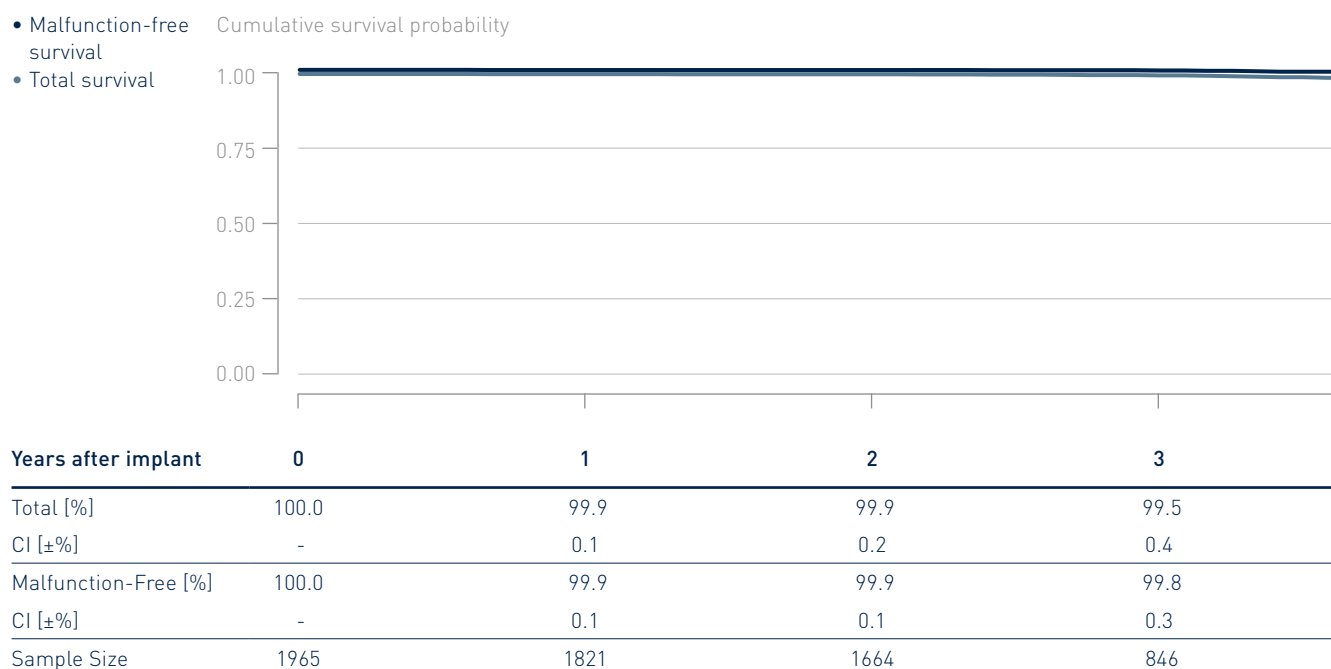
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Iperia 7

Product Versions	DR-T
NBG Codes	VDE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2710
Registered U.S. Implants	1965
Estimated Active U.S. Implants	1550
U.S. Normal Battery Depletions	9

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	7	0.36%
Therapy Compromised	4	0.20%
Therapy Available	3	0.15%



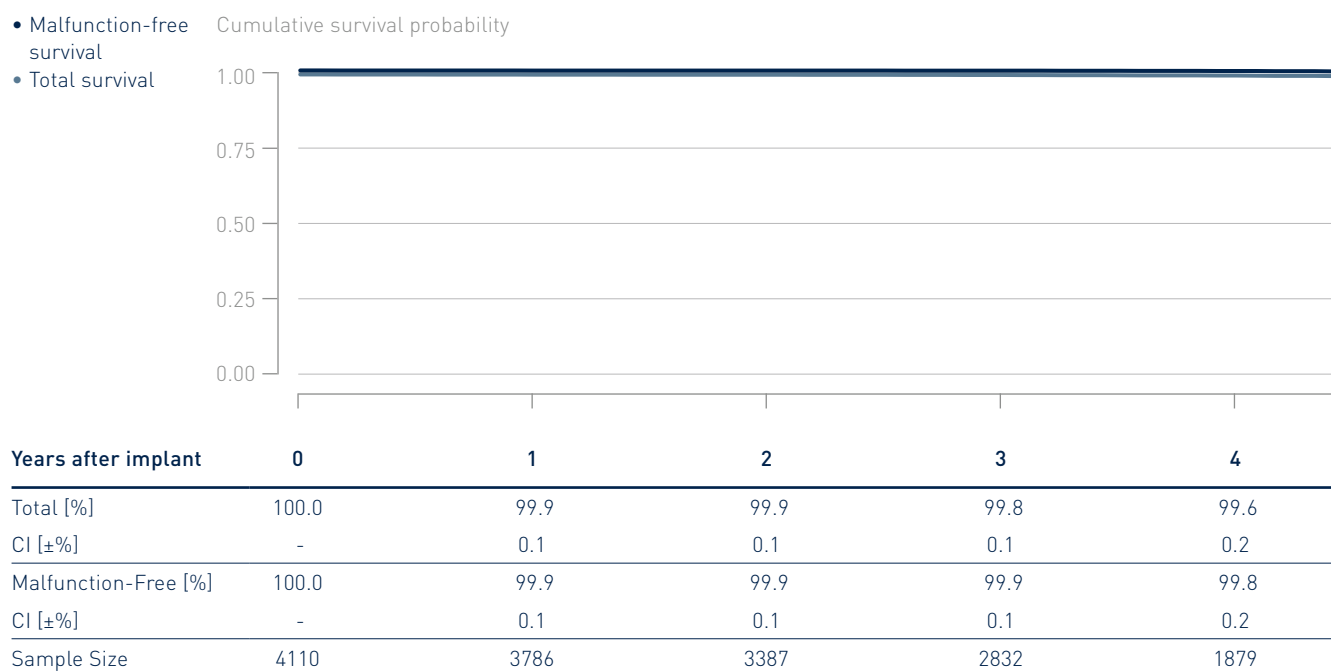
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Iperia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Dec 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	7 510
Registered U.S. Implants _____	4 110
Estimated Active U.S. Implants _____	3 120
U.S. Normal Battery Depletions _____	11

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	18	0.44%
Therapy Compromised _____	3	0.07%
Therapy Available _____	15	0.36%



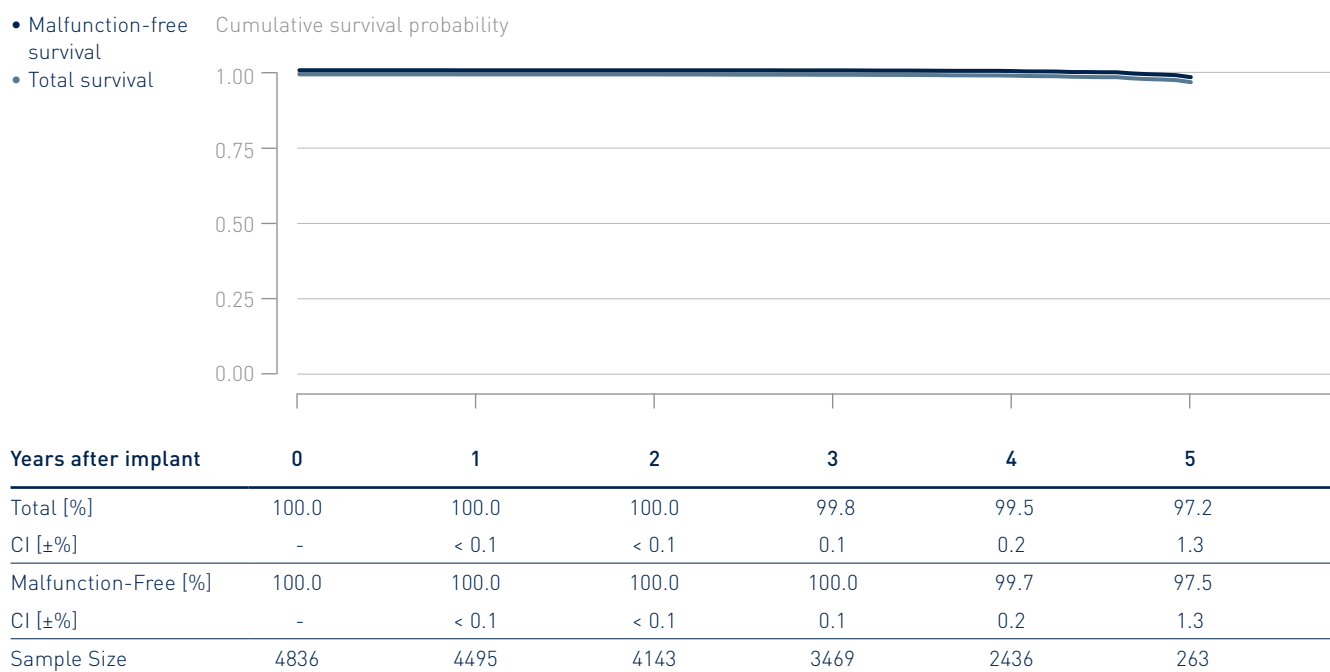
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Iperia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	6 540
Registered U.S. Implants	4 836
Estimated Active U.S. Implants	3 650
U.S. Normal Battery Depletions	16

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	28	0.58%
Therapy Compromised	8	0.17%
Therapy Available	20	0.41%



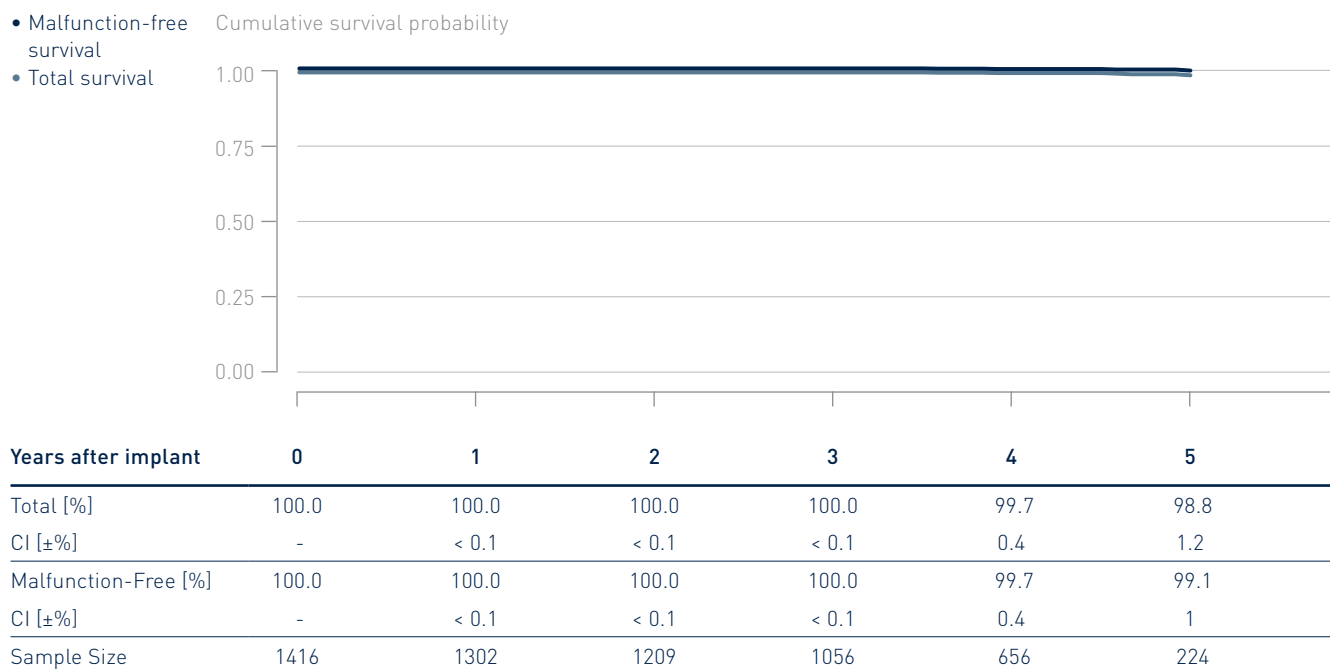
\* A subset of devices from this product family is subject to the advisory BIO-LQC.  
Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Itrevia 7

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2170
Registered U.S. Implants	1416
Estimated Active U.S. Implants	1040
U.S. Normal Battery Depletions	2

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	4	0.28%
Therapy Compromised	2	0.14%
Therapy Available	2	0.14%



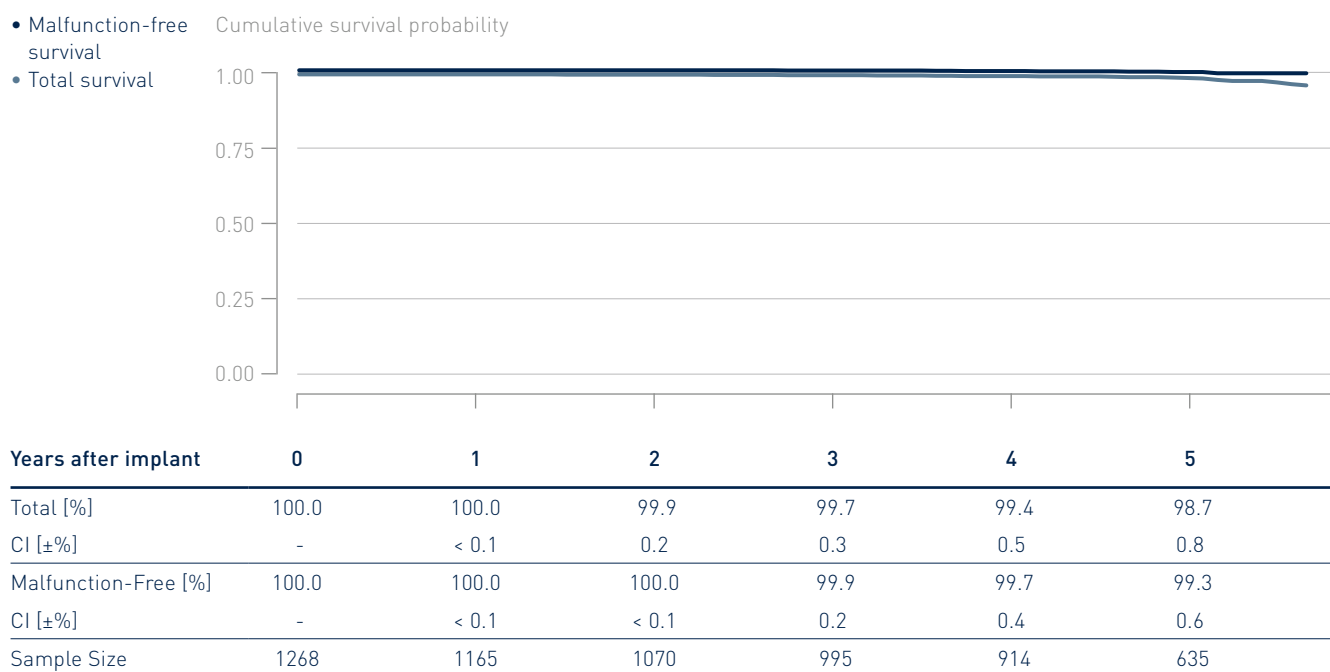
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Itrevia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	2340
Registered U.S. Implants _____	1268
Estimated Active U.S. Implants _____	847
U.S. Normal Battery Depletions _____	15

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	9	0.71%
Therapy Compromised _____	4	0.32%
Therapy Available _____	5	0.39%



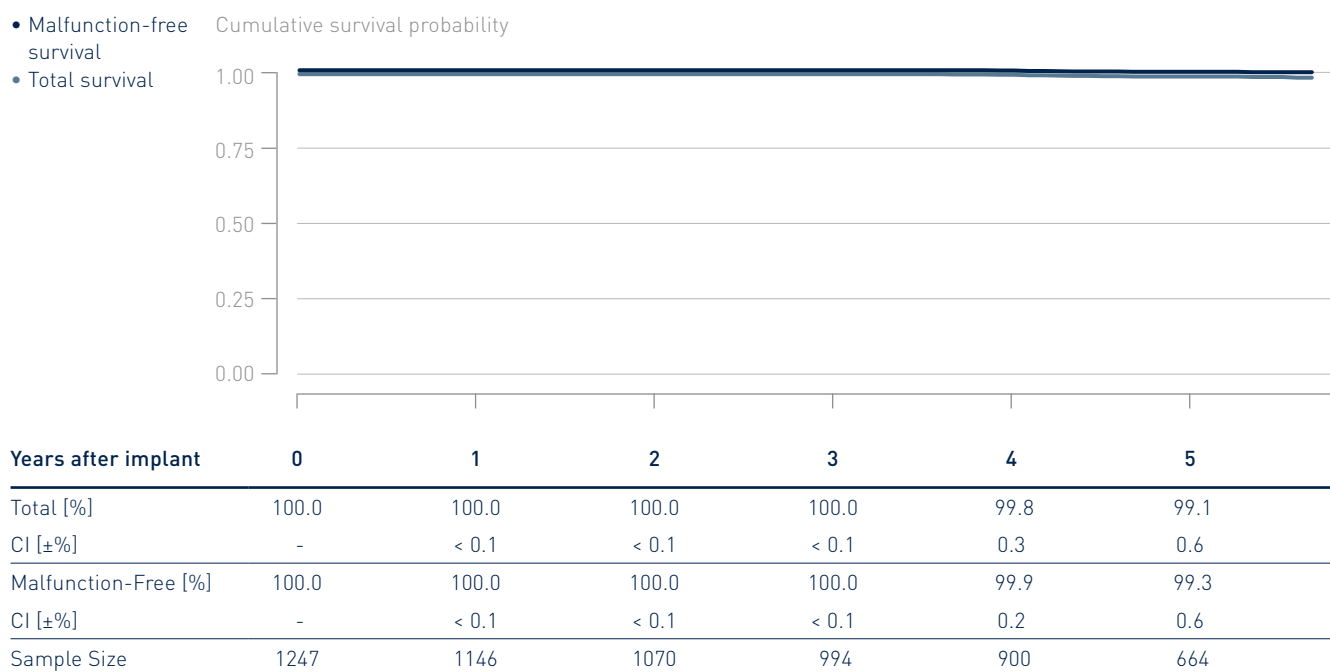
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Itrevia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2750
Registered U.S. Implants	1247
Estimated Active U.S. Implants	851
U.S. Normal Battery Depletions	5

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	7	0.56%
Therapy Compromised	2	0.16%
Therapy Available	5	0.40%



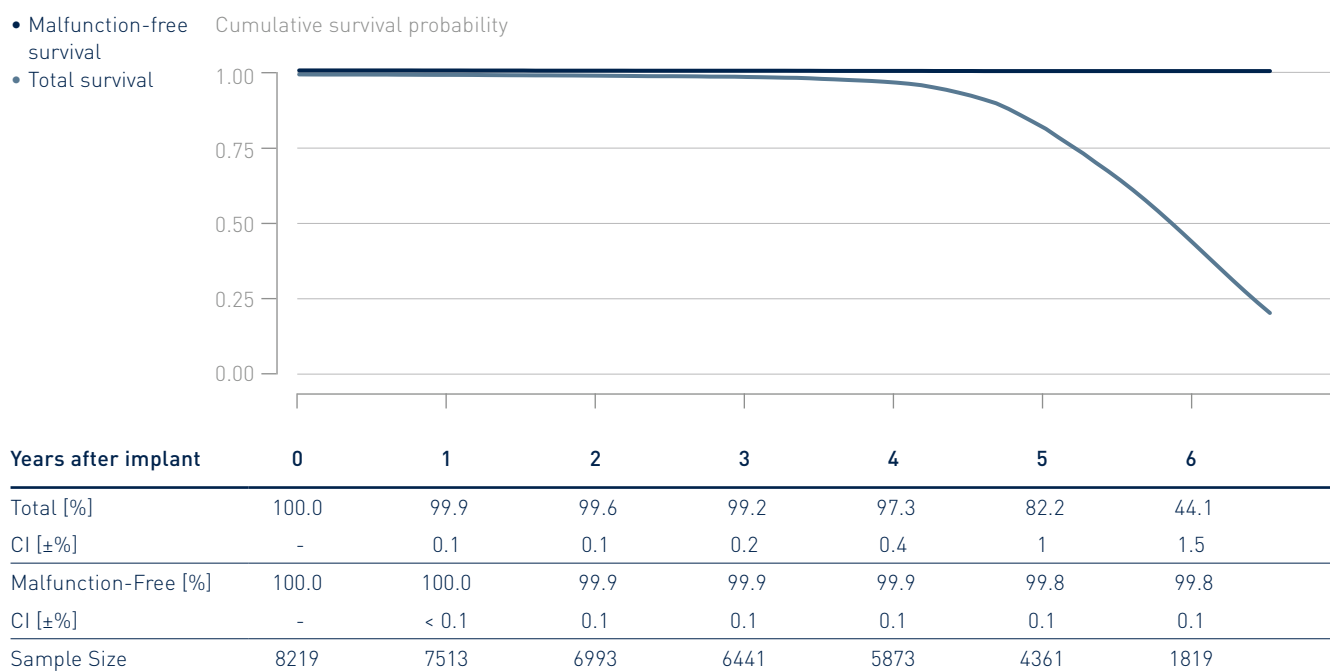
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.2 Dual-Chamber ICDs

### Lumax 340

Product Versions	DR, DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26400
Registered U.S. Implants	8219
Estimated Active U.S. Implants	1660
U.S. Normal Battery Depletions	2151

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	10	0.12%
Therapy Compromised	8	0.10%
Therapy Available	2	0.02%



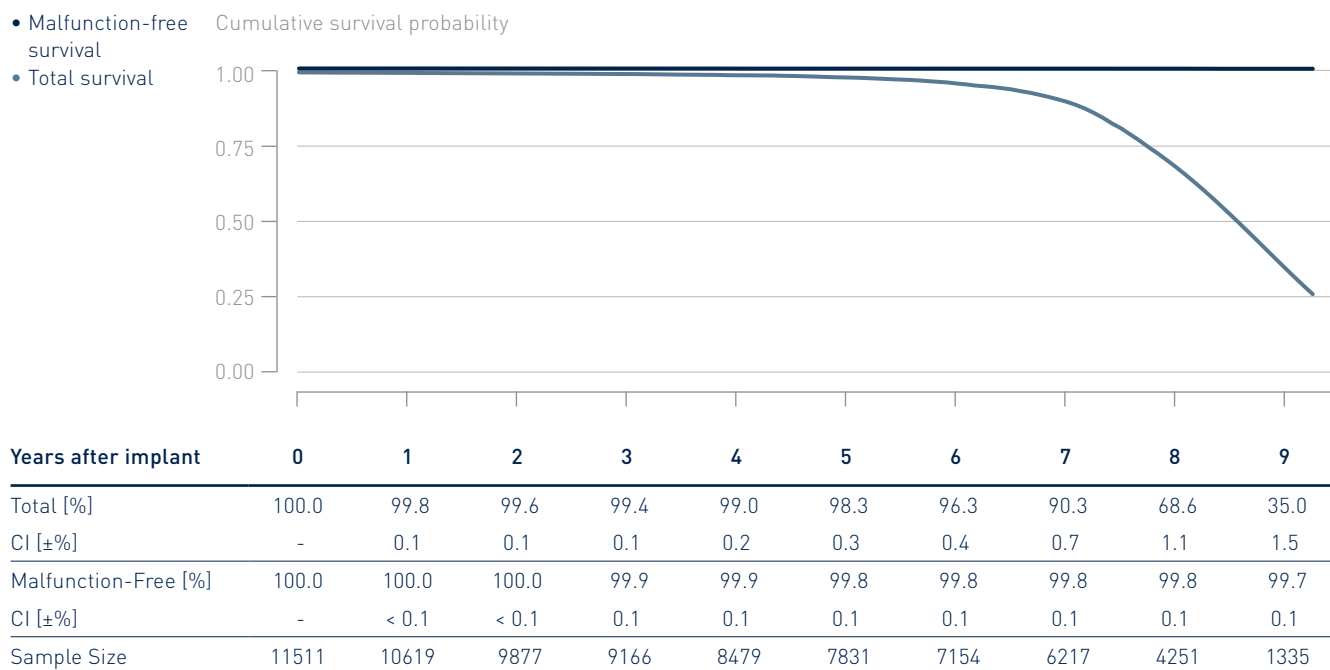


## 4.2 Dual-Chamber ICDs

### Lumax 540

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered U.S. Implants	11 511
Estimated Active U.S. Implants	2 950
U.S. Normal Battery Depletions	2 879

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	24	0.21%
Therapy Compromised	13	0.11%
Therapy Available	11	0.10%

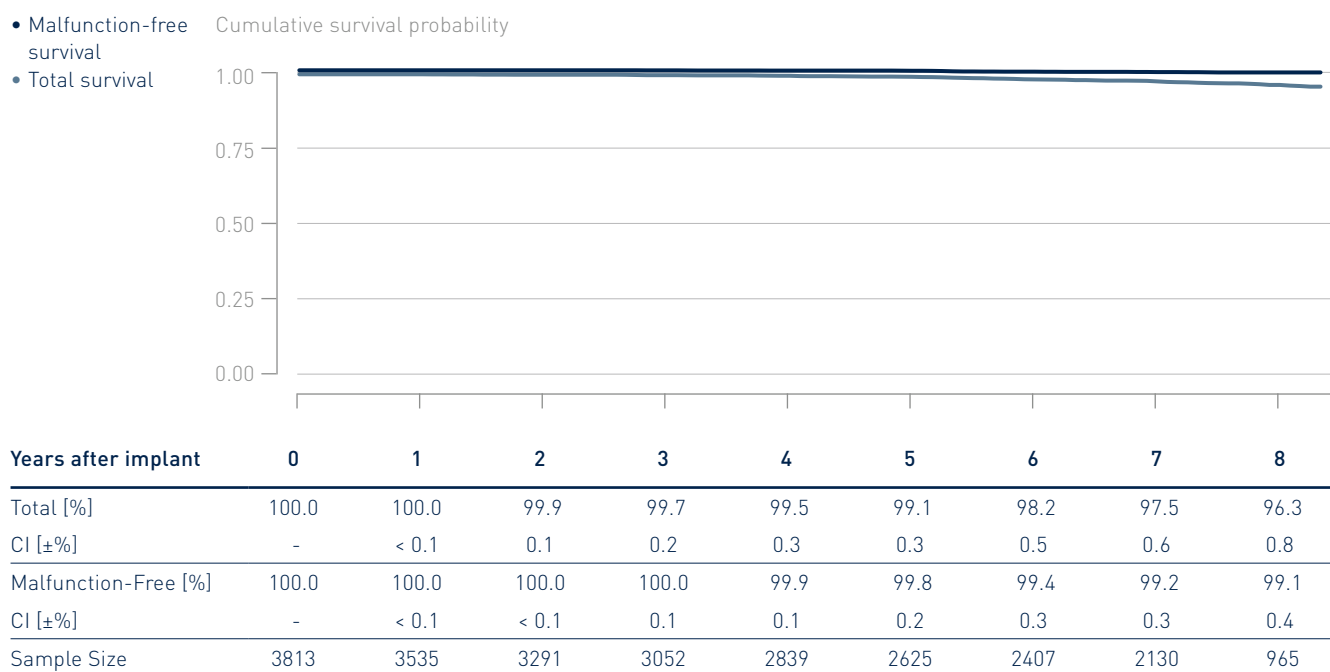


## 4.2 Dual-Chamber ICDs

### Lumax 740

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7 980
Registered U.S. Implants	3 813
Estimated Active U.S. Implants	2 200
U.S. Normal Battery Depletions	75

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	23	0.60%
Therapy Compromised	11	0.29%
Therapy Available	12	0.31%

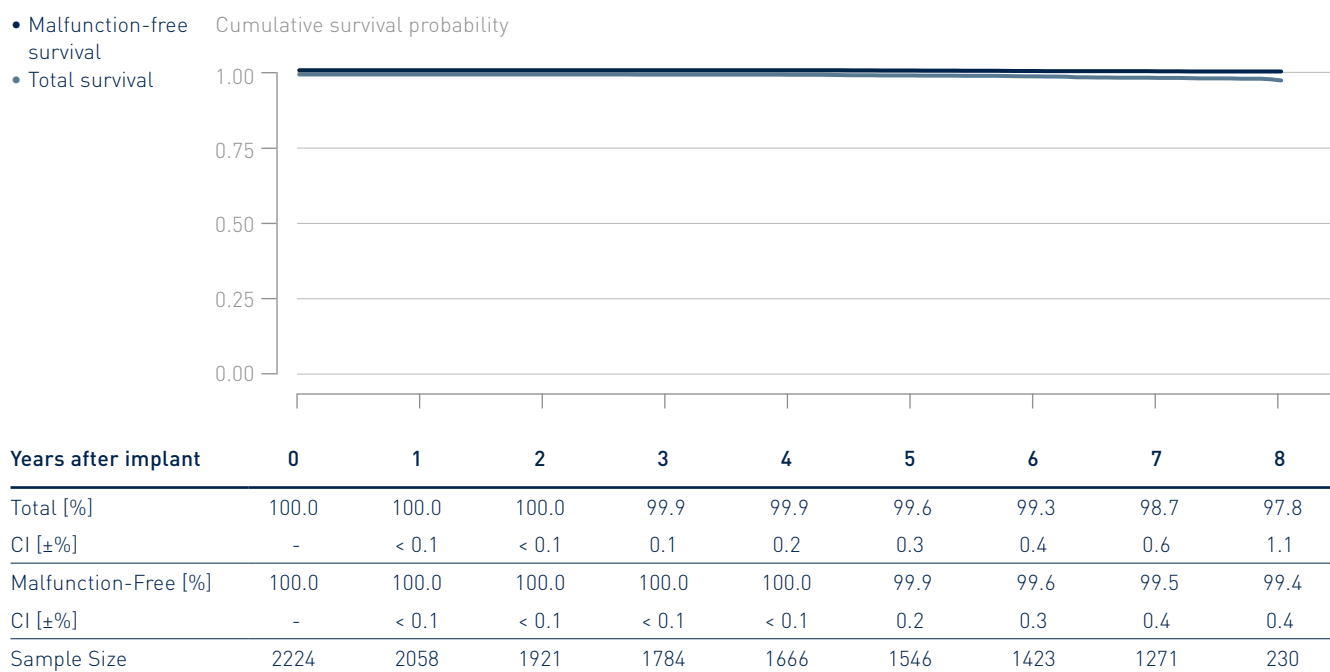


## 4.2 Dual-Chamber ICDs

### Lumax 740 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	May 2012
CE Market Release _____	Nov 2011
Worldwide Distributed Devices _____	4 560
Registered U.S. Implants _____	2 224
Estimated Active U.S. Implants _____	1 340
U.S. Normal Battery Depletions _____	16

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	9	0.40%
Therapy Compromised _____	3	0.13%
Therapy Available _____	6	0.27%

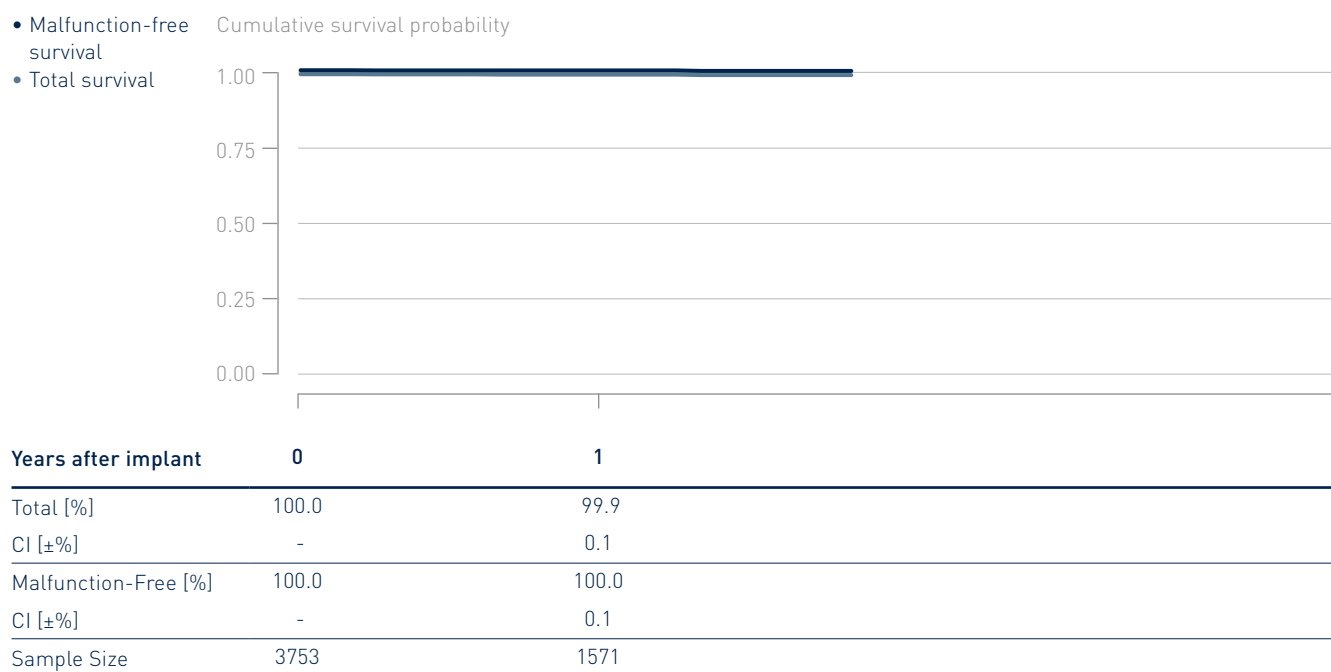


## 4.2 Dual-Chamber ICDs

### Rivacor 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Apr 2019
CE Market Release _____	Mar 2019
Worldwide Distributed Devices _____	7 270
Registered U.S. Implants _____	3 753
Estimated Active U.S. Implants _____	3 510
U.S. Normal Battery Depletions _____	1

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b> _____	2	0.05%
Therapy Compromised _____	2	0.05%
Therapy Available _____	0	0.00%

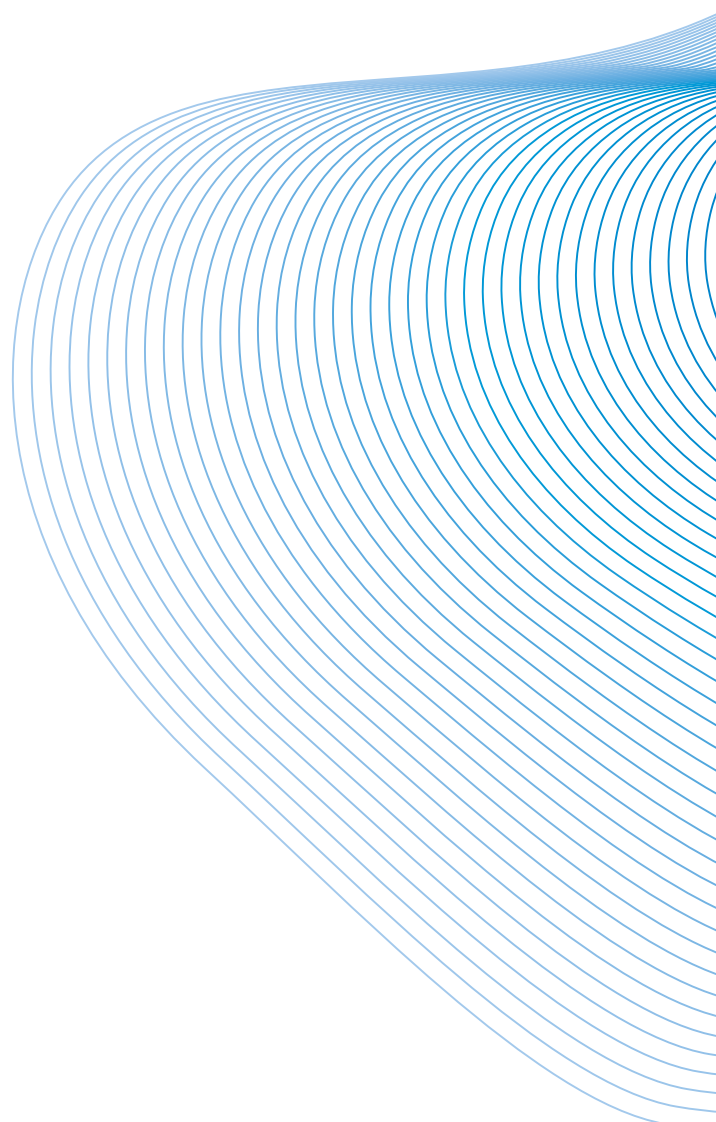


# Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

**4.3 CRT ICDs**



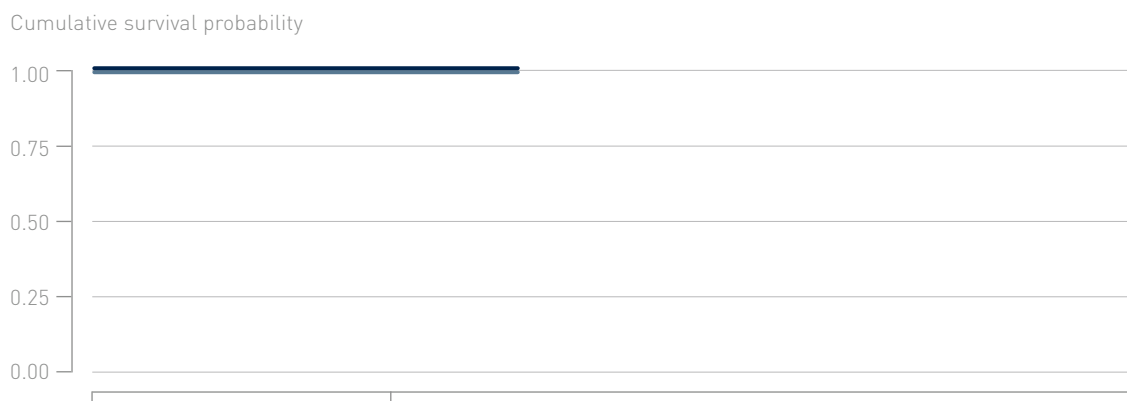
## 4.3 CRT ICDs

### Acticor 7

Product Versions	HF-T, HF-T QP
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	7 990
Registered U.S. Implants	1 795
Estimated Active U.S. Implants	1 620
U.S. Normal Battery Depletions	0

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	1	0.06%
Therapy Compromised	1	0.06%
Therapy Available	0	0.00%

- Malfunction-free survival
- Total survival



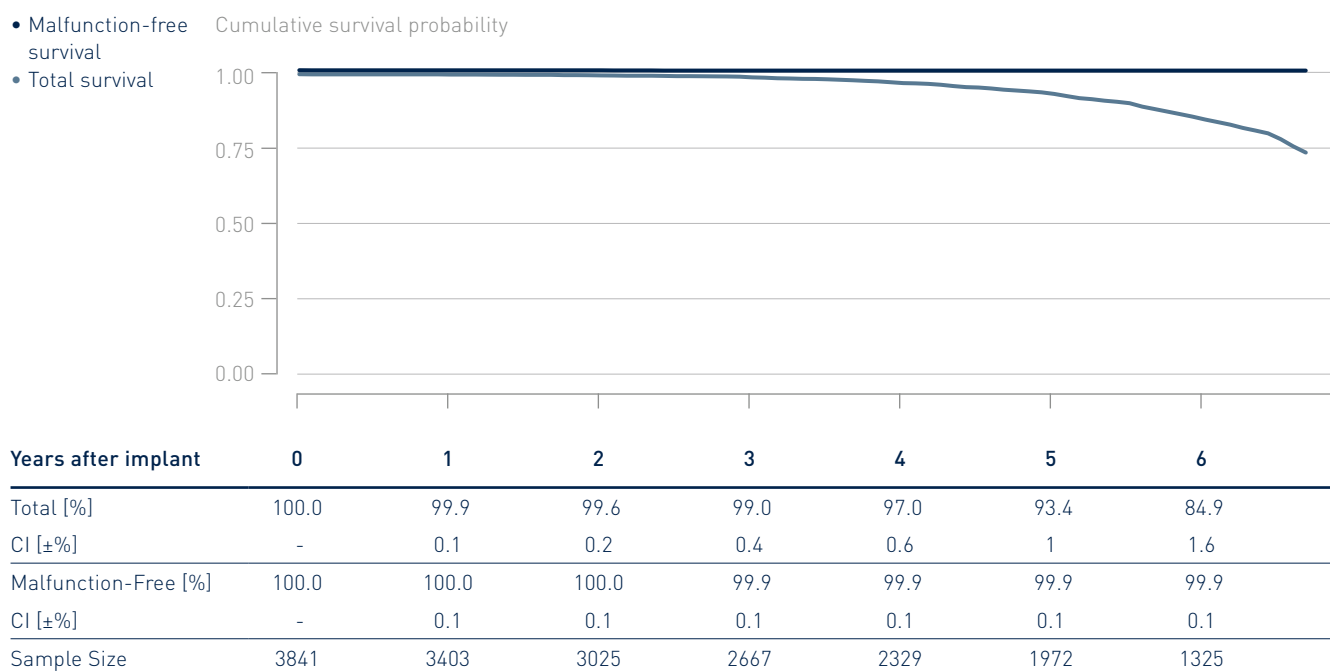
Years after implant	0	1
Total [%]	99.9	99.9
CI [±%]	-	0.1
Malfunction-Free [%]	99.9	99.9
CI [±%]	-	0.1
Sample Size	1795	569

## 4.3 CRT ICDs

### Ilesto 7

Product Versions	HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5290
Registered U.S. Implants	3841
Estimated Active U.S. Implants	1540
U.S. Normal Battery Depletions	399

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	3	0.08%
Therapy Compromised	2	0.05%
Therapy Available	1	0.03%



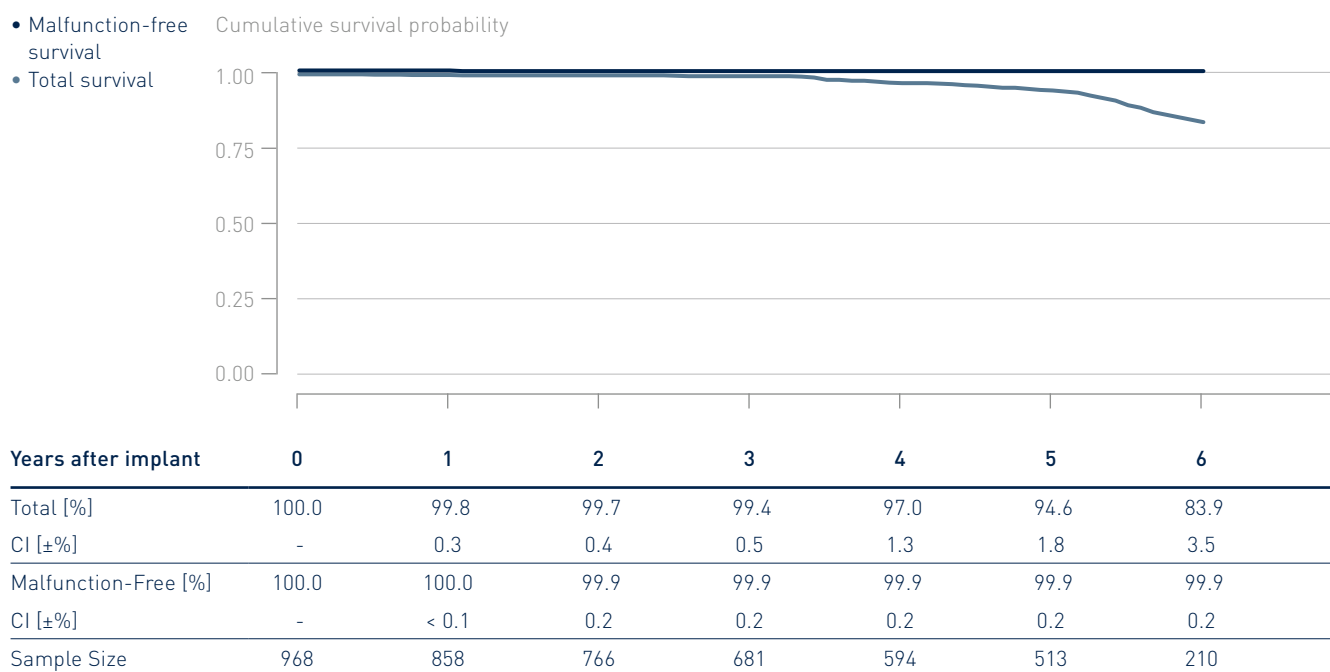
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Ilesto 7 DF4

Product Versions _____	HF-T
NBG Codes _____	WE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Jul 2014
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2360
Registered U.S. Implants _____	968
Estimated Active U.S. Implants _____	460
U.S. Normal Battery Depletions _____	74

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	1	0.10%
Therapy Compromised _____	1	0.10%
Therapy Available _____	0	0.00%



\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

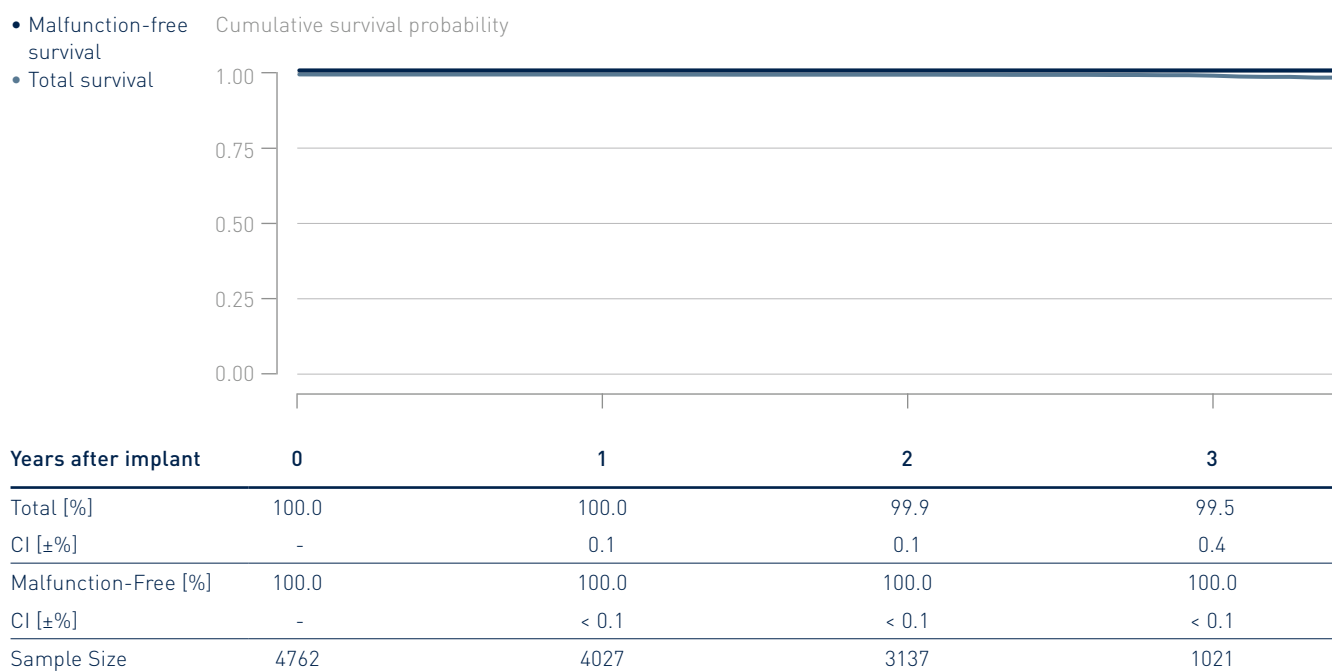


## 4.3 CRT ICDs

### Ilivia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	9 290
Registered U.S. Implants	4 762
Estimated Active U.S. Implants	3 500
U.S. Normal Battery Depletions	16

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



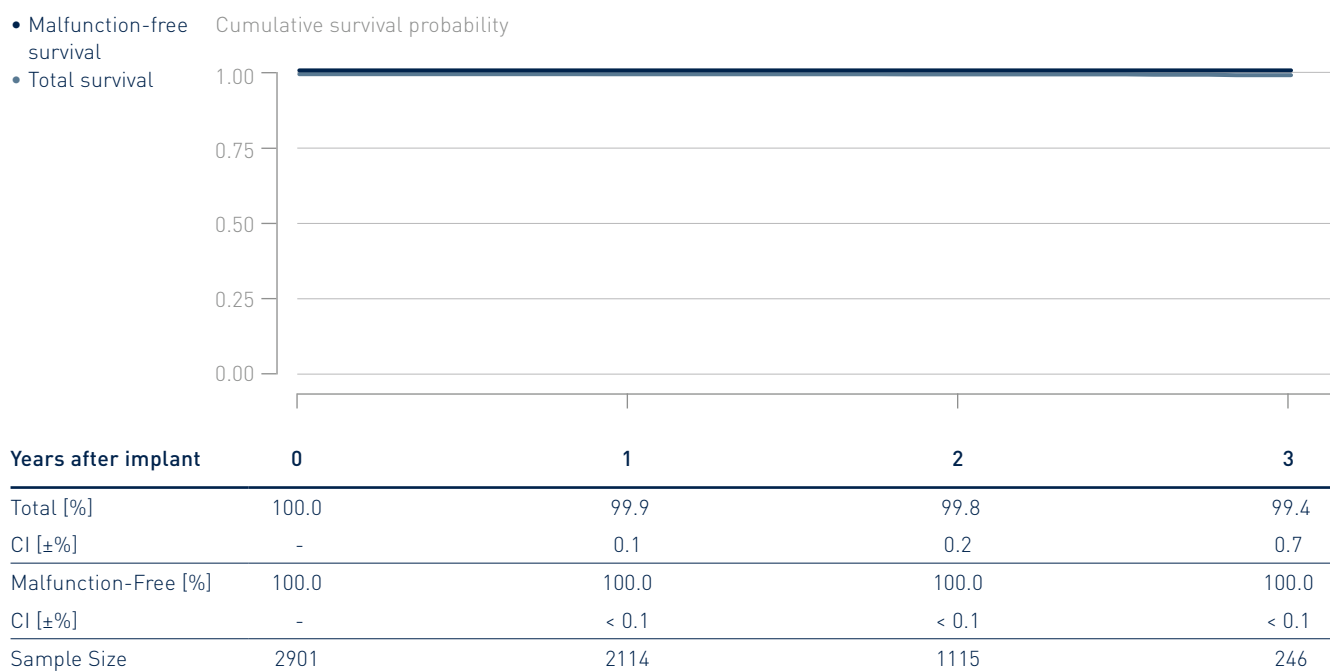
\* A subset of devices from this product family is subject to the advisory BIO-LQC.  
Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Intica 7 DF1

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Sep 2016
Worldwide Distributed Devices _____	5460
Registered U.S. Implants _____	2901
Estimated Active U.S. Implants _____	2260
U.S. Normal Battery Depletions _____	5

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	0	0.00%
Therapy Compromised _____	0	0.00%
Therapy Available _____	0	0.00%



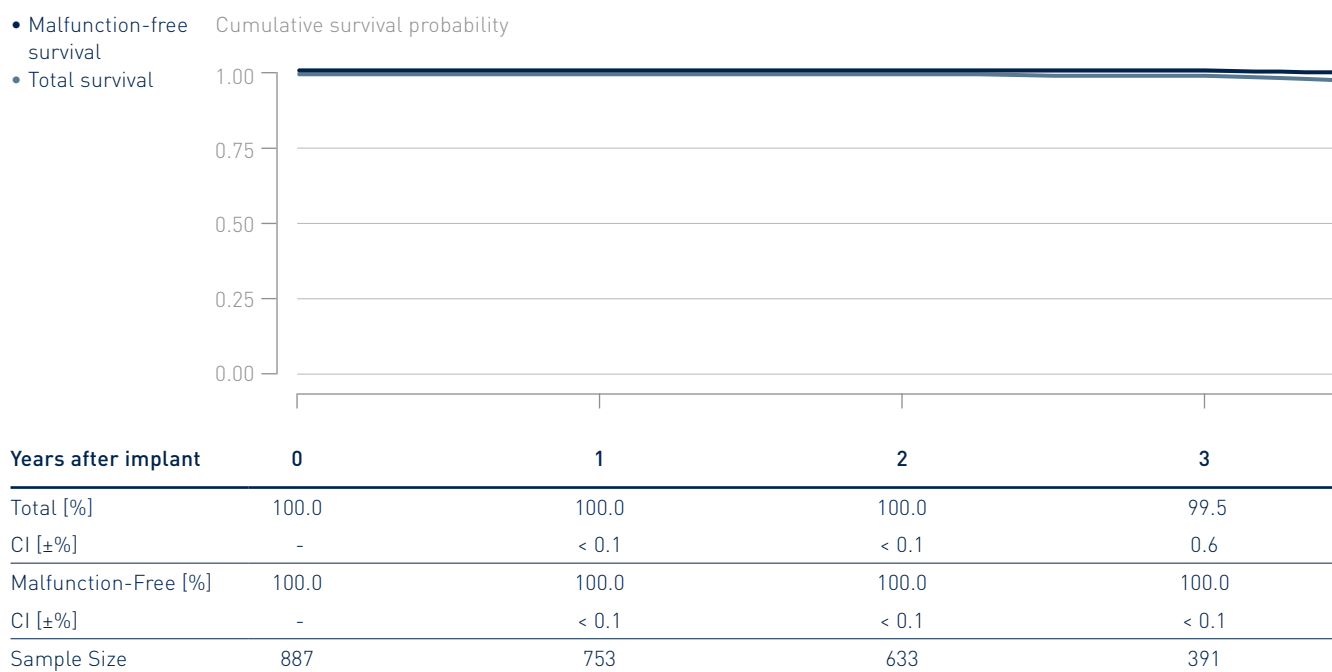
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Inventra 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	45
US Market Release	Aug 2014
CE Market Release	Jul 2014
Worldwide Distributed Devices	2 110
Registered U.S. Implants	887
Estimated Active U.S. Implants	604
U.S. Normal Battery Depletions	7

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	4	0.45%
Therapy Compromised	0	0.00%
Therapy Available	4	0.45%



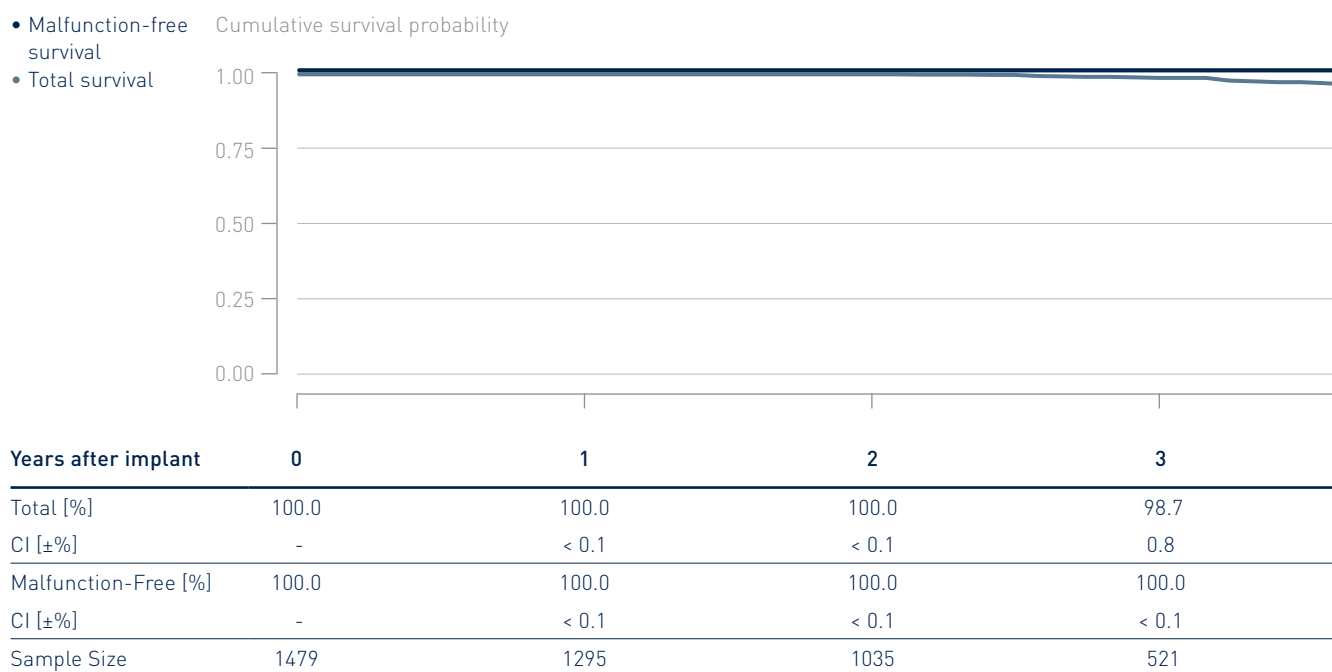
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Iperia 7

Product Versions _____	HF-T
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Apr 2016
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	3040
Registered U.S. Implants _____	1479
Estimated Active U.S. Implants _____	1020
U.S. Normal Battery Depletions _____	22

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b> _____	0	0.00%
Therapy Compromised _____	0	0.00%
Therapy Available _____	0	0.00%



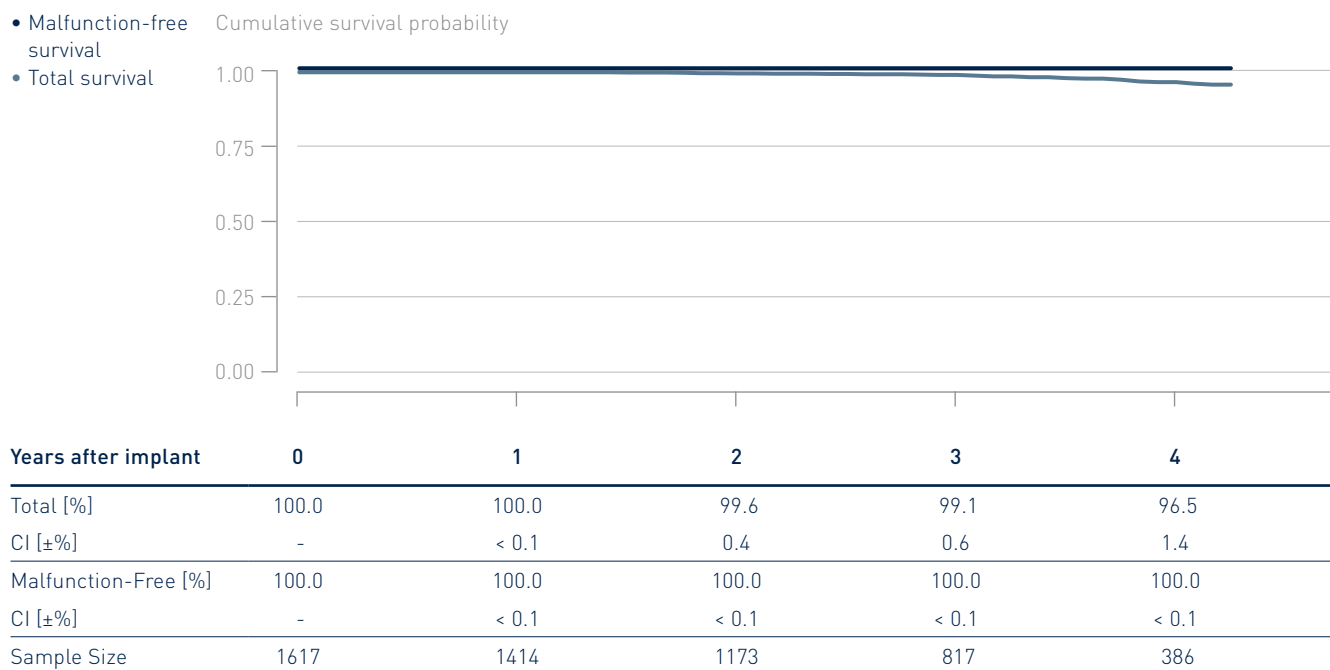
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Iperia 7 DF4

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	5830
Registered U.S. Implants	1617
Estimated Active U.S. Implants	1080
U.S. Normal Battery Depletions	31

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



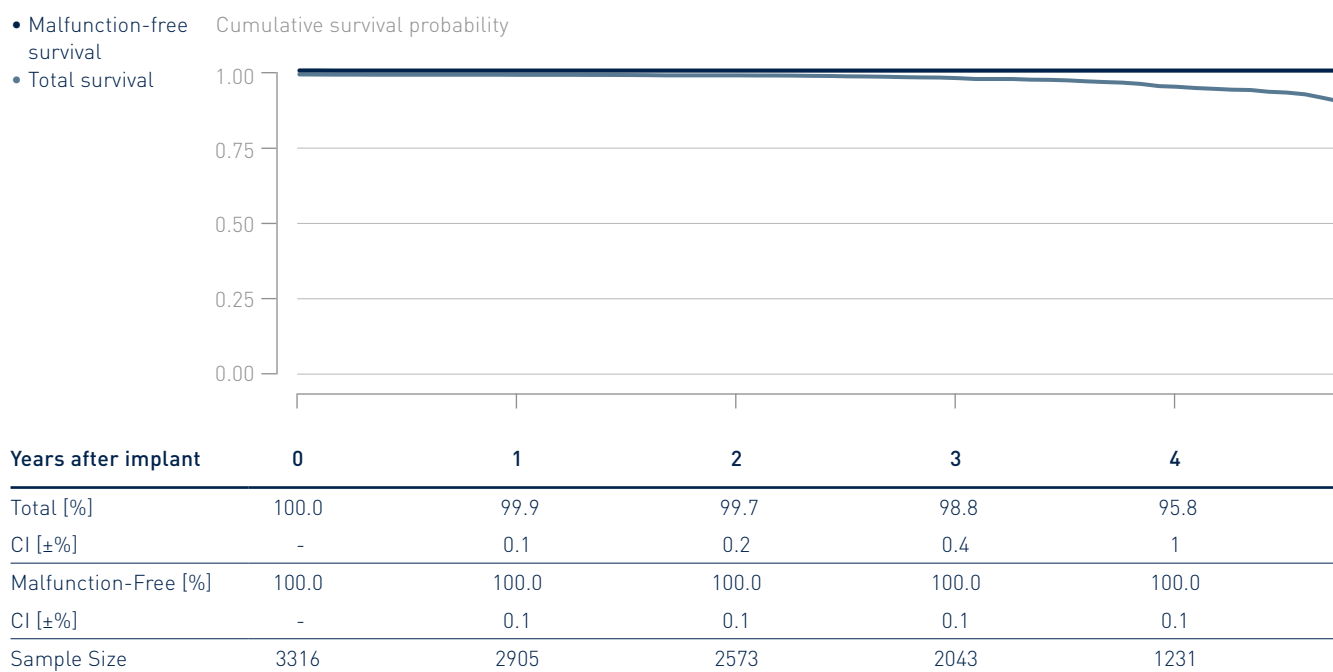
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Itrevia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	4 600
Registered U.S. Implants	3316
Estimated Active U.S. Implants	1900
U.S. Normal Battery Depletions	131

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	1	0.03%
Therapy Compromised	0	0.00%
Therapy Available	1	0.03%



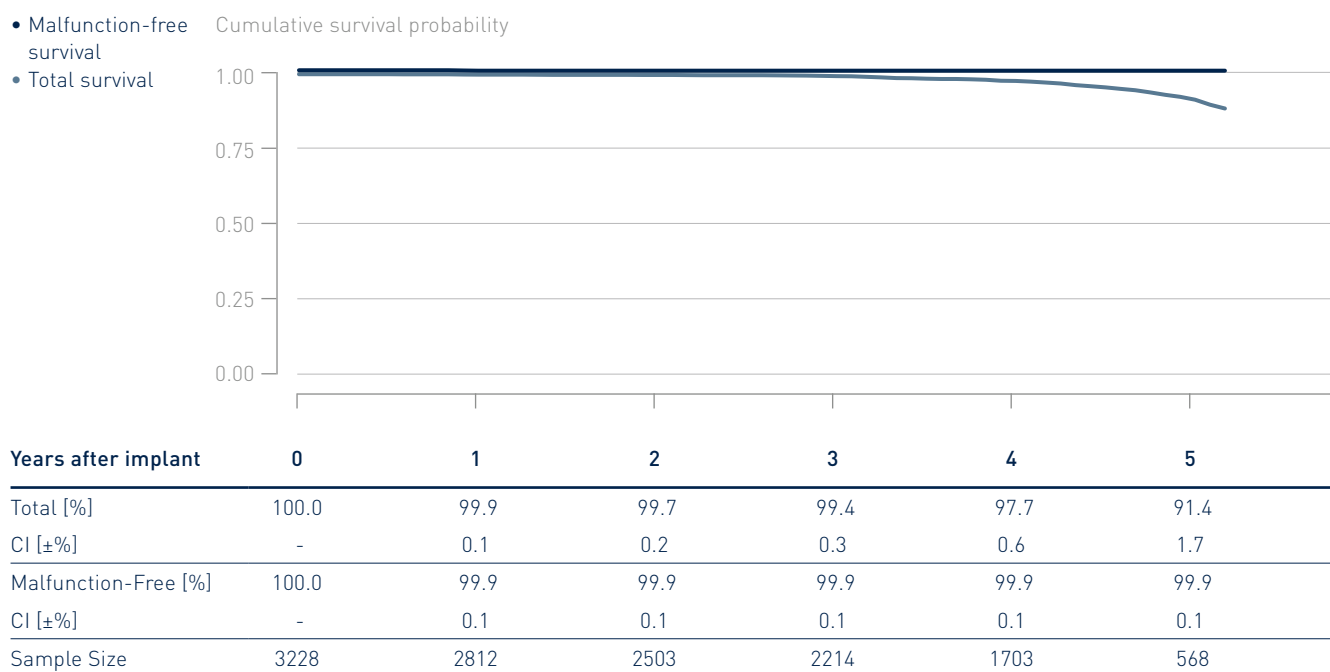
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Itrevia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 680
Registered U.S. Implants	3 228
Estimated Active U.S. Implants	1 740
U.S. Normal Battery Depletions	131

	Quantity	Rate
<b>U.S. Confirmed Malfunctions*</b>	2	0.06%
Therapy Compromised	0	0.00%
Therapy Available	2	0.06%



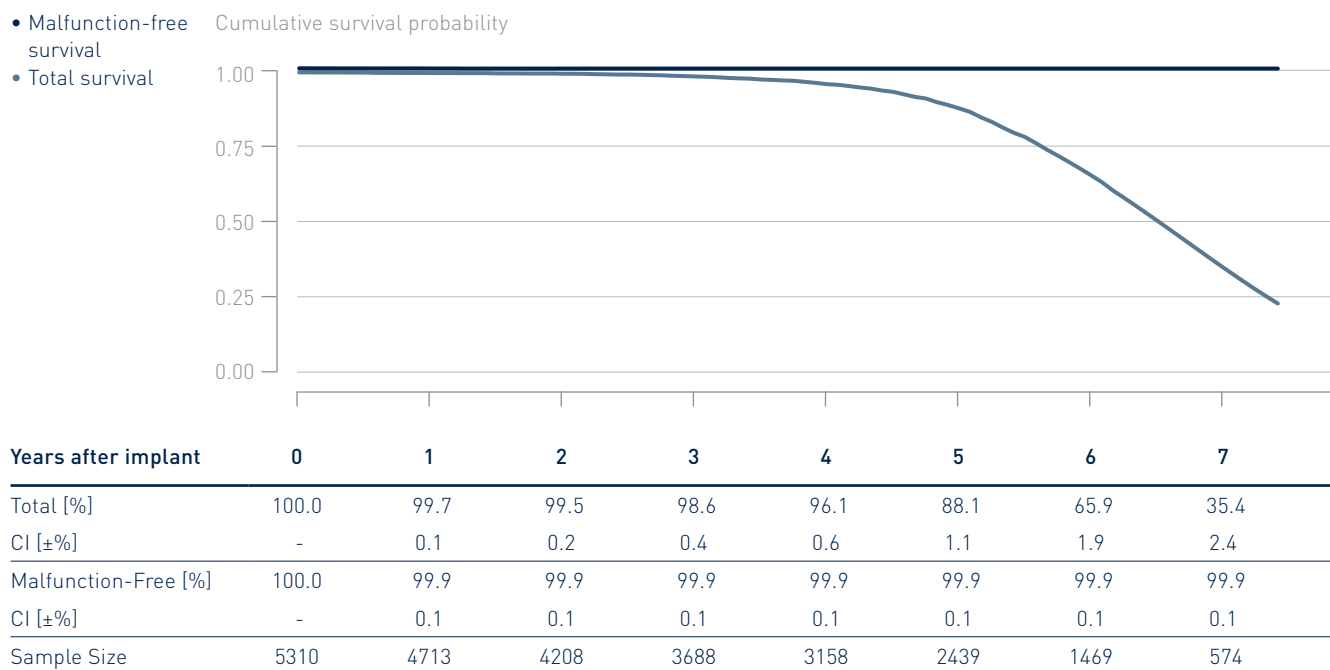
\* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

## 4.3 CRT ICDs

### Lumax 340

Product Versions	HF, HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20 700
Registered U.S. Implants	5310
Estimated Active U.S. Implants	509
U.S. Normal Battery Depletions	1 269

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	4	0.08%
Therapy Compromised	2	0.04%
Therapy Available	2	0.04%



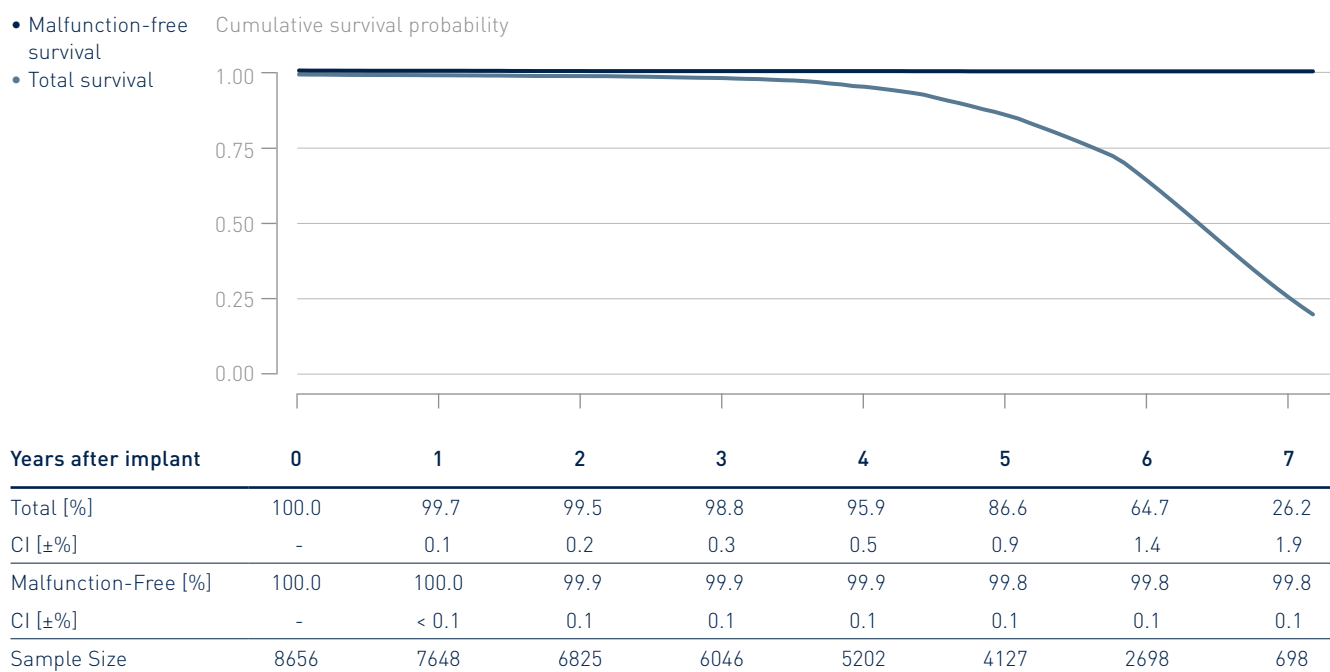


## 4.3 CRT ICDs

### Lumax 540

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	24 800
Registered U.S. Implants	8 656
Estimated Active U.S. Implants	987
U.S. Normal Battery Depletions	2 586

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	11	0.13%
Therapy Compromised	5	0.06%
Therapy Available	6	0.07%

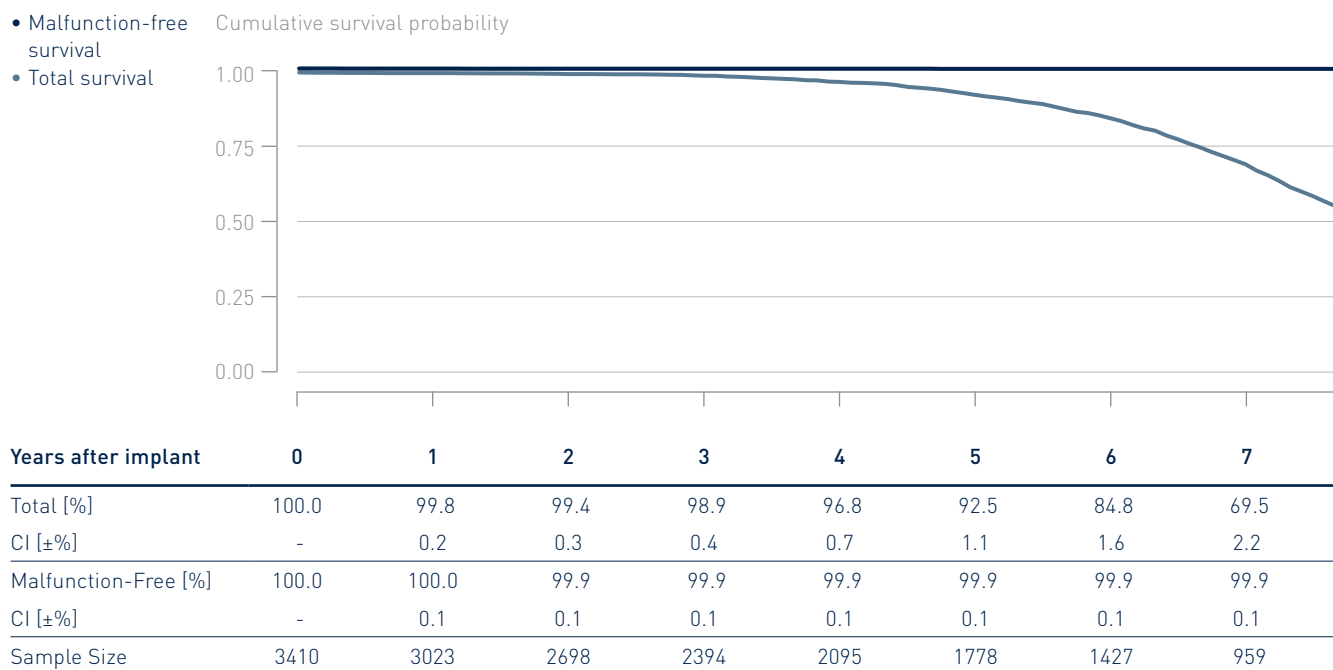


## 4.3 CRT ICDs

### Lumax 740

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7040
Registered U.S. Implants	3410
Estimated Active U.S. Implants	822
U.S. Normal Battery Depletions	691

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	3	0.09%
Therapy Compromised	1	0.03%
Therapy Available	2	0.06%



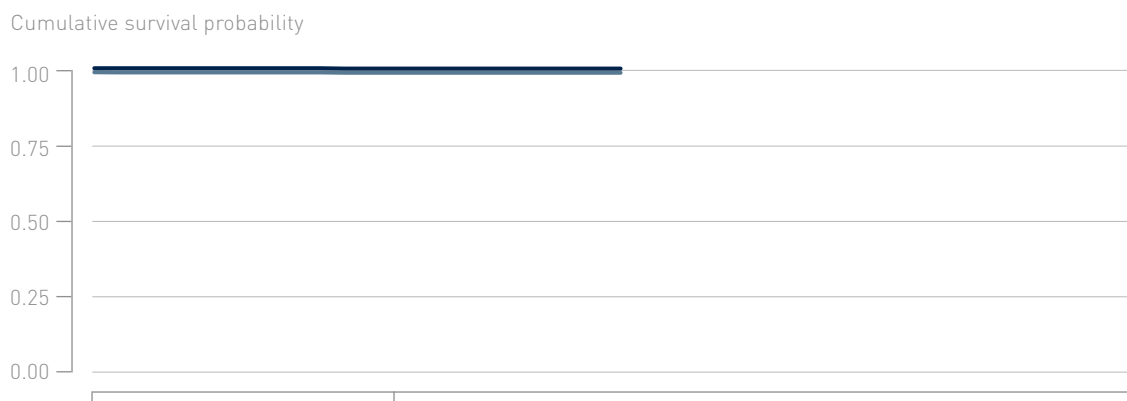
## 4.3 CRT ICDs

### Rivacor 7 DF4

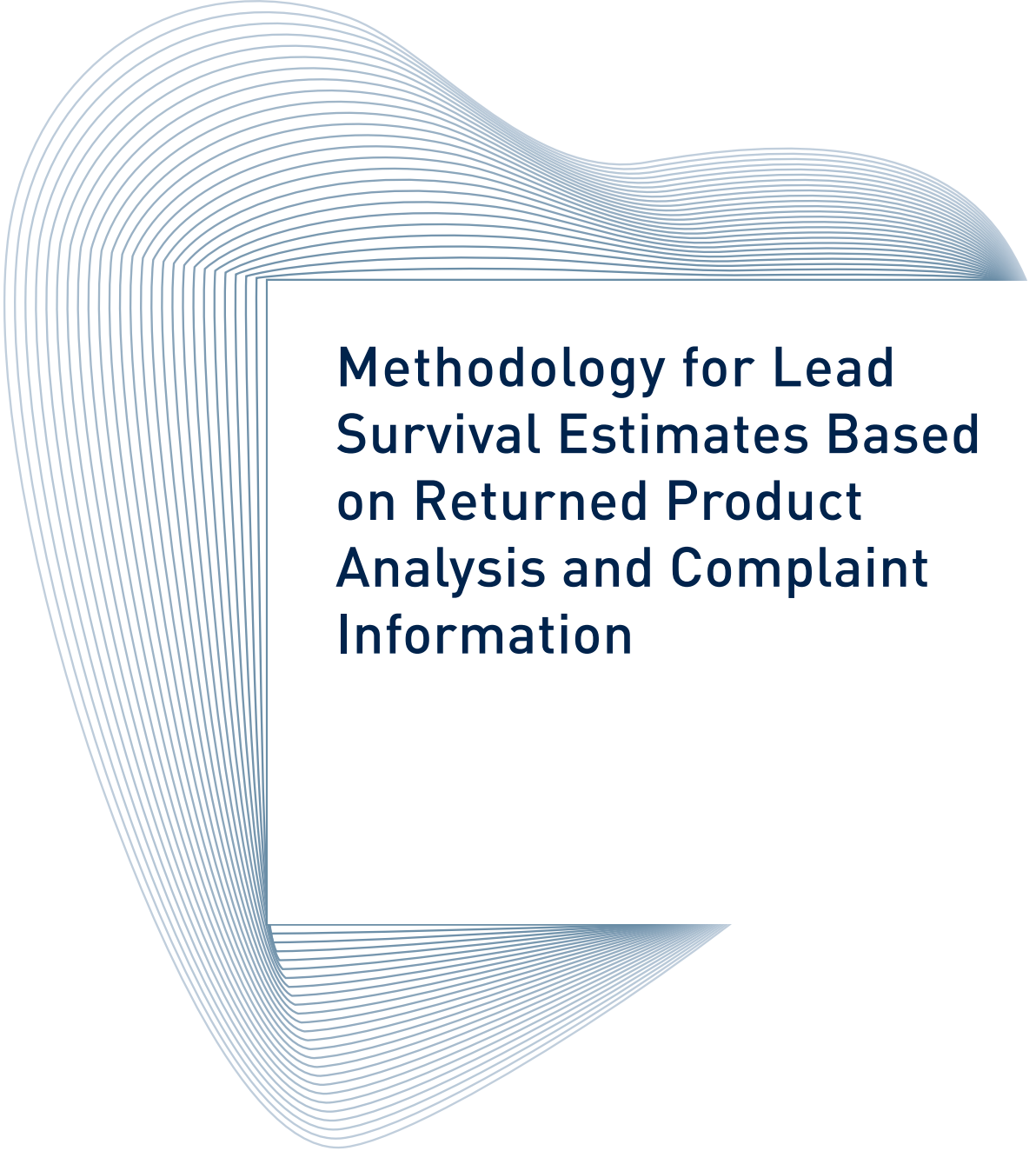
Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	8 770
Registered U.S. Implants	3 447
Estimated Active U.S. Implants	3 080
U.S. Normal Battery Depletions	1

	Quantity	Rate
<b>U.S. Confirmed Malfunctions</b>	1	0.03%
Therapy Compromised	1	0.03%
Therapy Available	0	0.00%

- Malfunction-free survival
- Total survival



Years after implant	0	1
Total [%]	100.0	99.9
CI [±%]	-	0.1
Malfunction-Free [%]	100.0	99.9
CI [±%]	-	0.1
Sample Size	3447	1441



## **Methodology for Lead Survival Estimates Based on Returned Product Analysis and Complaint Information**

# 5. Methodology for Lead Survival Estimates Based on Returned Product Analysis and Complaint Information

## 5.1 Cumulative Lead Survival Probability

This report has been prepared in accordance with ISO 5841-2:2014(E) applying actuarial analysis for the calculation of lead survival probabilities based on returned product analysis. Lead survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK's pacing and ICD leads.

The cumulative survival probability for leads is an estimate based on the percentage of devices that remain implanted and in service at various points of the product's service time in the absence of concurrent events such as morbidity. The lead survival estimate over time is displayed in cumulative survival curves (Kaplan-Meier). The product's performance is evaluated in discrete one-month intervals. The survival probability for each month is given by the number of leads that remain implanted and active through this month divided by the number of leads that were actively implanted at the start of the interval. The cumulative survival probability for any period is given by multiplying all survival probabilities of previous months.

At the time of implantation, the cumulative lead survival probability is 100%. Even though they are analyzed as part of our quality system monitoring, leads that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time.

Because this report is provided to communicate information regarding product performance, it does not include data regarding medical complications such as erosion, infection or diaphragmatic stimulation.

Compared to pacemakers and ICDs, a considerable portion of leads with observed or suspected failures are not explanted and returned for laboratory analysis. This is primarily because it is much more difficult and risky to the patient to remove chronically implanted leads. In order to report a conservative measure of lead performance, unconfirmed reports of lead complications are therefore also included in the calculation of a lead's survival probability.

In order to be classified as a qualifying lead complication and thus contributing to the survival probability calculation the same way as a confirmed malfunction, the reported anomaly must have occurred at least 30 days post-implant. Otherwise, factors not related to the lead would likely be the root cause of the observed anomaly, (i.e., patient specific conditions or implant techniques).

In order to minimize the effect of underreporting of lead malfunctions, BIOTRONIK additionally includes the long term performance post market study data if available.

## 5.2 Lead Data Acquisition

The following sections of this report provide performance data on BIOTRONIK's pacing and ICD leads and are based on the observation of BIOTRONIK's U.S. products through review of our device registration and tracking systems, and through the analyses of both, returned leads as well as reports of lead complications of non-returned leads. The prospective data from BIOTRONIK's post-approval studies is presented separately in chapters 7 and 8.

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is June 30, 2021. The sample sizes of U.S. leads that are implanted and remain active as well as the total number of products distributed worldwide are provided for each lead family in this report.

Survival estimates are calculated for lead families having accumulated at least 10,000 cumulative implant months. Products no longer being distributed with less than 500 active implants may be excluded from this report.

ISO 5841-2:2014(E) describes a method for adjusting the device survival probability for underreported malfunctions and unrelated patient deaths that result in an overestimation of the device's survival probability. The factor for U.S. underreporting of malfunctions of pacing and ICD leads is unknown as currently no systematic data is available that reveals this factor. Consequently, this factor remains unaccounted for in this report. Patient mortality is artificially elevated if the reported rate from our registration and tracking systems is below the annual mortality in clinical studies.

## 5.3 Returned Product Analysis

Information for the lead sections of this report is taken from the analysis of returned products. The outcome of this analysis is the basis for the final classification of the cause for explantation of the lead. Additionally, reports of lead complications not confirmed by laboratory analysis are taken into consideration. Both, leads with confirmed malfunctions as well as unconfirmed lead complications decrease a lead's total survival probability.

Every lead and lead segment returned to BIOTRONIK is analyzed per our internal procedures and classified as within specification, damaged by external causes, or out of specification (malfunction) while implanted and in service.

Those leads found to be out of specification, are divided into the following categories as proposed by AdvaMed and ISO 5841-2:2014(E):

### **Conductor Fracture**

Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors)

### **Crimps, Welds and Bonds**

Any interruption in the conductor or lead body associated with a point of connection

### **Insulation Breach**

Any lead insulation breach

### **Other**

Includes specific proprietary lead mechanical attributes.

## 5.4 Lead Complications

A considerable portion of leads with observed or suspected failures are not explanted and returned for laboratory analysis. A clinical observation is considered a lead complication if a complaint, associated with at least one of the clinical manifestations listed below, is reported and where the non-returned lead is:

- Verified by medical records to have been implanted and in-service, and
- Reported to have been removed from service,
- Modified surgically or electrically to remedy the malfunction, or
- Left in service based on medical judgment.

Complications for leads implanted greater than 30 days are reported as qualifying lead complications, whereas complications occurring during the first 30 days are reported as acute lead observations.

In accordance with the latest AdvaMed guidelines and ISO 5841-2:2014(E) such clinical observations are classified in the following categories:

### **Failure to Capture**

Intermittent or complete failure to achieve cardiac stimulation at programmed output delivered outside of the cardiac refractory period. Sudden and significant increase in the pacing threshold value at which 2:1 safety margin can no longer be achieved.

### **Failure to Sense**

Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals during non-refractory periods at programmed sensitivity settings

### **Oversensing**

Misinterpretation of cardiac or non-cardiac events as cardiac depolarization

### **Abnormal Pacing Impedance**

Pacing impedance is typically considered abnormal if a measurement is < 200 ohms or > 3000 ohms

### **Abnormal Defibrillation Impedance**

Defibrillation impedance is typically considered abnormal if a measurement is < 20 ohms or > 200 ohms. Including high or low shock impedance when attempting to deliver a shock

### **Insulation Breach**

A disruption or break in lead insulation observed visually, electrically, or radiographically

### **Conductor Fracture**

A mechanical break within the lead conductor observed visually, electrically, or radiographically

### **Lead Dislodgement**

Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance

### **Extracardiac Stimulation**

Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle

### **Cardiac Perforation**

Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance, chest pain, and tamponade

### **Other**

Specific proprietary attributes of a lead such as sensors which affect a lead's ability to perform as designed or remain in service

In order to report a conservative measure of lead performance, qualifying lead complications are also included in the calculation of a lead's survival probability.

Acute Lead Observations may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. Therefore, acute lead observations are not included in lead survival probability.

## **5.5 Lead Product Performance Graphs and Data**

The lead performance information is shown in each section in alphabetical order and by product name.

For each lead, the report provides:

- Product versions that contribute to the evaluation
- Types of leads
- Polarity
- Steroid
- CE and U.S. market release dates
- Worldwide quantity of products that have been distributed
- U.S. registered implants (number of products included in this report)
- Estimated active U.S. implants
- Number of U.S. qualifying complications

- Number of U.S. acute lead observations
- Number of U.S. confirmed malfunctions
- Number of U.S. leads or partial leads returned post-implant for analysis with a complaint

The survival plots provide:

### **Total Survival**

The cumulative survival probability free of component malfunction or unconfirmed observation of an anomaly. Removals for clinical reasons unrelated to the device's performance (i.e., infections) are excluded.

Products or subgroups of products may become subject to advisory notifications that can significantly impact the overall product performance.

Current advisories are listed in chapter 11 of this report, however to date, BIOTRONIK has never had a pacing or ICD lead safety advisory notification, therefore no summary of lead advisories is provided.

The cumulative survival data and the 95 % confidence intervals according to the Greenwood's formula<sup>1</sup> are shown in numerical form for the observed sample population.

<sup>1</sup> Greenwood, M. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1-26, 1926

## Performance of BIOTRONIK Leads

Based on Returned Products  
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads





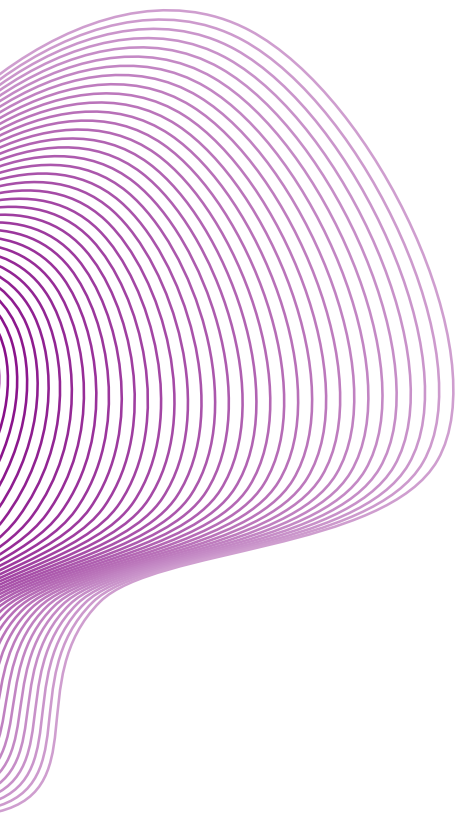
# Performance of BIOTRONIK Leads

Based on Returned Products  
and Complaint Data

## 6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



## 6.1 Pacing Leads

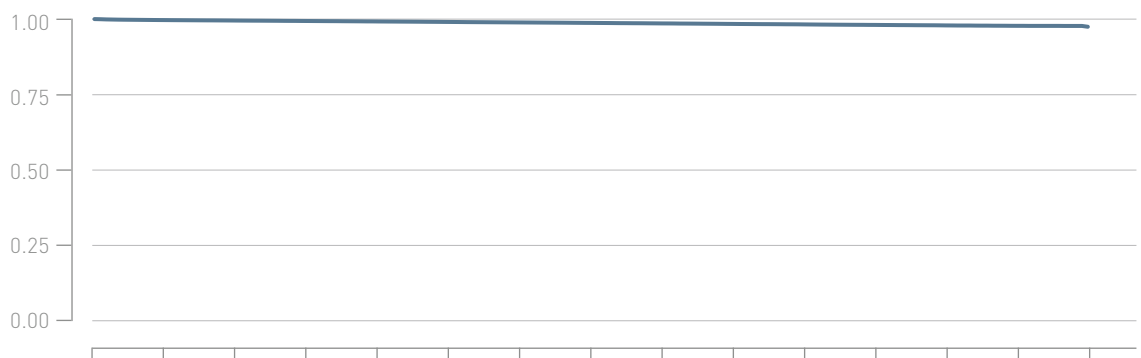
### Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	480 000
Registered U.S. Implants	379 526
Estimated Active U.S. Implants	224 000
U.S. Total Returned	2412

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	4 587	1.19%	<b>U.S. Confirmed Malfunctions</b>	368	0.10%
Abnormal Pacing Impedance	417	0.11%	Conductor Fracture	126	0.03%
Cardiac Perforation	25	0.01%	Insulation Breach	236	0.06%
Conductor Fracture	126	0.03%	Other	6	0.00%
Extracardiac Stimulation	22	0.01%			
Failure to Capture	1 154	0.30%	<b>U.S. Acute Lead Observations</b>	1 718	0.45%
Failure to Sense	175	0.05%	Abnormal Pacing Impedance	43	0.01%
Insulation Breach	88	0.02%	Cardiac Perforation	70	0.02%
Lead Dislodgement	561	0.15%	Extracardiac Stimulation	15	0.00%
Oversensing	1202	0.31%	Failure to Capture	250	0.07%
Other	817	0.21%	Failure to Sense	66	0.02%
			Insulation Breach	10	0.00%
			Lead Dislodgement	692	0.18%
			Oversensing	46	0.01%
			Other	526	0.14%

#### • Total survival

Cumulative survival probability



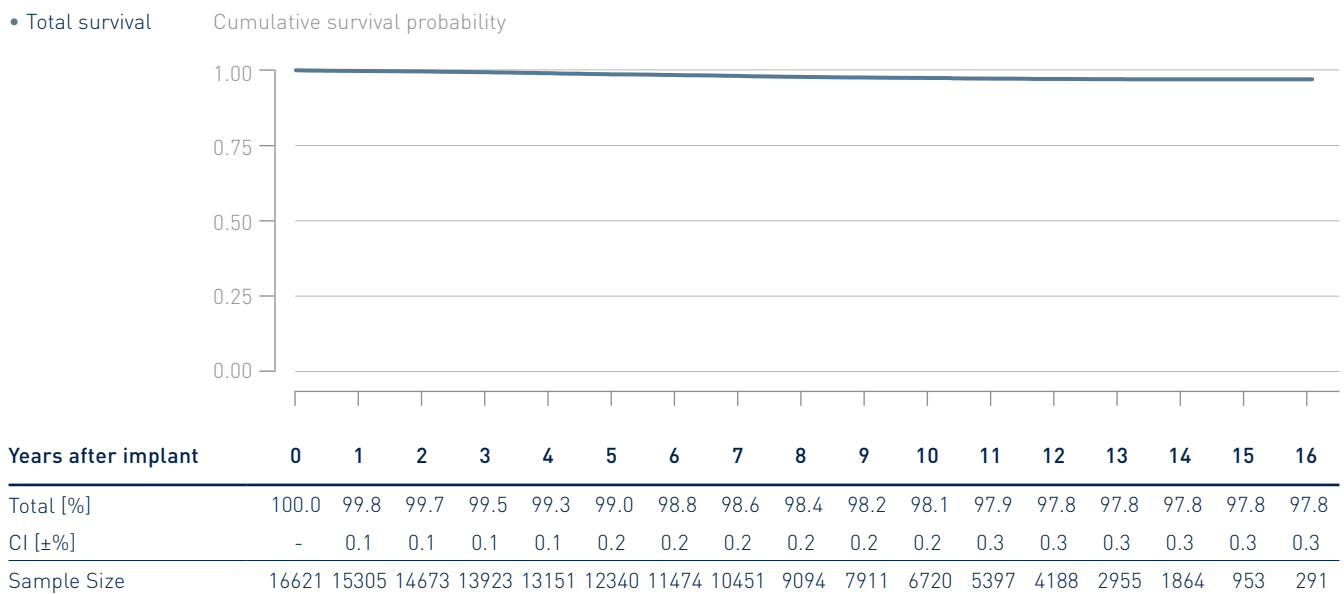
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.6	99.5	99.3	99.1	99.0	98.8	98.6	98.4	98.3	98.1	97.9	97.7	97.6	97.2
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.6
Sample Size	379526	336459	314863	295548	278157	260580	219542	177018	138716	106626	80128	56162	33765	14277	335

## 6.1 Pacing Leads

### Selox JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	157 000
Registered U.S. Implants	16 621
Estimated Active U.S. Implants	12 300
U.S. Total Returned	127

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	239	1.44%	<b>U.S. Confirmed Malfunctions</b>	10	0.06%
Abnormal Pacing Impedance	35	0.21%	Insulation Breach	10	0.06%
Cardiac Perforation	1	0.01%			
Conductor Fracture	11	0.07%	<b>U.S. Acute Lead Observations</b>	45	0.27%
Extracardiac Stimulation	1	0.01%	Failure to Capture	8	0.05%
Failure to Capture	105	0.63%	Lead Dislodgement	34	0.20%
Failure to Sense	9	0.05%	Other	3	0.02%
Insulation Breach	12	0.07%			
Lead Dislodgement	37	0.22%			
Oversensing	9	0.05%			
Other	19	0.11%			



## 6.1 Pacing Leads

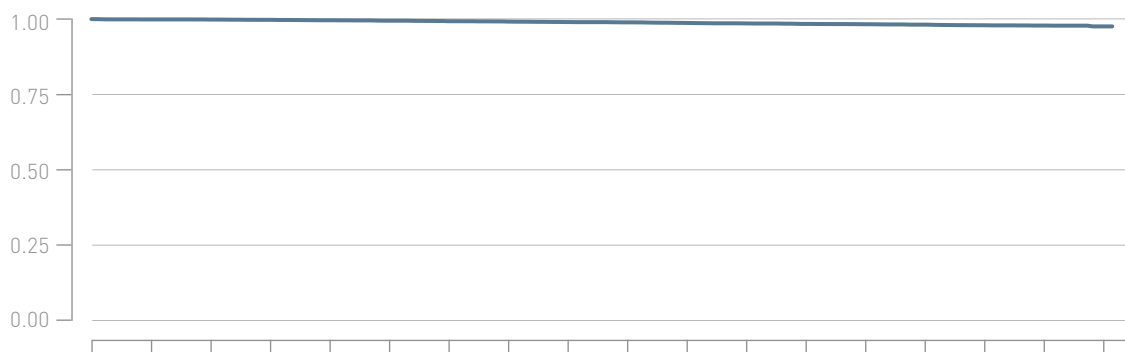
### Selox SR

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2004
CE Market Release	Feb 2004
Worldwide Distributed Devices	172 000
Registered U.S. Implants	14 344
Estimated Active U.S. Implants	7 030
U.S. Total Returned	63

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	126	0.88%	<b>U.S. Confirmed Malfunctions</b>	13	0.09%
Abnormal Pacing Impedance	10	0.07%	Insulation Breach	13	0.09%
Conductor Fracture	12	0.08%			
Extracardiac Stimulation	2	0.01%	<b>U.S. Acute Lead Observations</b>	21	0.15%
Failure to Capture	46	0.32%	Cardiac Perforation	1	0.01%
Failure to Sense	1	0.01%	Failure to Capture	11	0.08%
Insulation Breach	6	0.04%	Insulation Breach	1	0.01%
Lead Dislodgement	14	0.10%	Lead Dislodgement	8	0.06%
Oversensing	21	0.15%			
Other	14	0.10%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6	98.5	98.4	98.2
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.4
Sample Size	14344	12432	11658	10861	10043	9355	8736	8238	7880	7607	7398	7220	7131	7065	6999	6873	3743	638

## 6.1 Pacing Leads

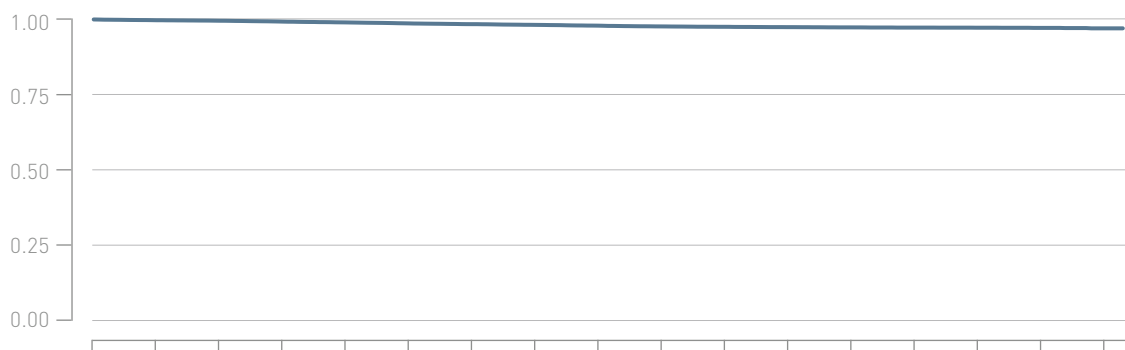
### Selox ST

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	379 000
Registered U.S. Implants	32 137
Estimated Active U.S. Implants	22 700
U.S. Total Returned	181

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	627	1.95%	<b>U.S. Confirmed Malfunctions</b>	19	0.06%
Abnormal Pacing Impedance	143	0.44%	Conductor Fracture	1	0.00%
Cardiac Perforation	3	0.01%	Crimps, Welds and Bonds	1	0.00%
Conductor Fracture	65	0.20%	Insulation Breach	17	0.05%
Extracardiac Stimulation	6	0.02%			
Failure to Capture	305	0.95%	<b>U.S. Acute Lead Observations</b>	49	0.15%
Failure to Sense	1	0.00%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	39	0.12%	Failure to Capture	21	0.07%
Lead Dislodgement	24	0.07%	Lead Dislodgement	21	0.07%
Oversensing	13	0.04%	Other	6	0.02%
Other	28	0.09%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.5	97.4	97.2	97.2	97.1	97.0	97.0	96.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3
Sample Size	32137	29233	27723	26073	24557	23044	21480	19668	17243	14994	12610	10214	8119	6008	4080	2304	707

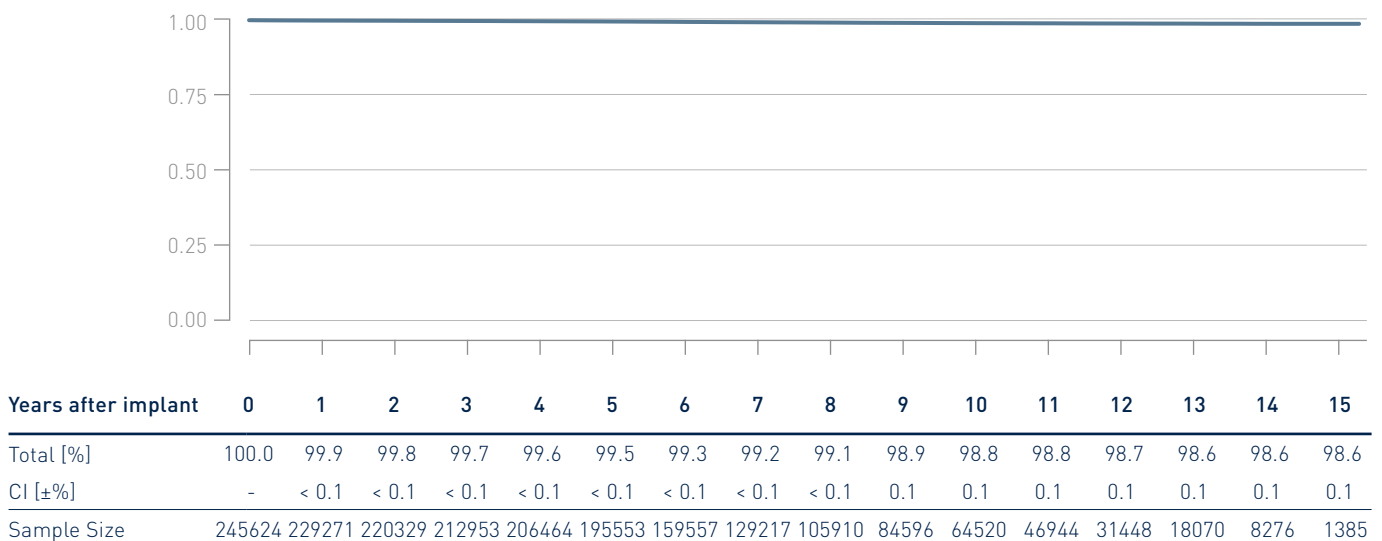
## 6.1 Pacing Leads

### Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	681 000
Registered U.S. Implants	245 624
Estimated Active U.S. Implants	196 000
U.S. Total Returned	1 713

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	1 846	0.75%	<b>U.S. Confirmed Malfunctions</b>	197	0.08%
Abnormal Pacing Impedance	161	0.07%	Conductor Fracture	62	0.03%
Cardiac Perforation	9	0.00%	Insulation Breach	130	0.05%
Conductor Fracture	116	0.05%	Other	5	0.00%
Extracardiac Stimulation	12	0.00%			
Failure to Capture	637	0.26%	<b>U.S. Acute Lead Observations</b>	273	0.11%
Failure to Sense	54	0.02%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	83	0.03%	Cardiac Perforation	24	0.01%
Lead Dislodgement	351	0.14%	Failure to Capture	35	0.01%
Oversensing	298	0.12%	Failure to Sense	3	0.00%
Other	125	0.05%	Insulation Breach	4	0.00%
			Lead Dislodgement	189	0.08%
			Oversensing	1	0.00%
			Other	16	0.01%

• Total survival Cumulative survival probability



## 6.1 Pacing Leads

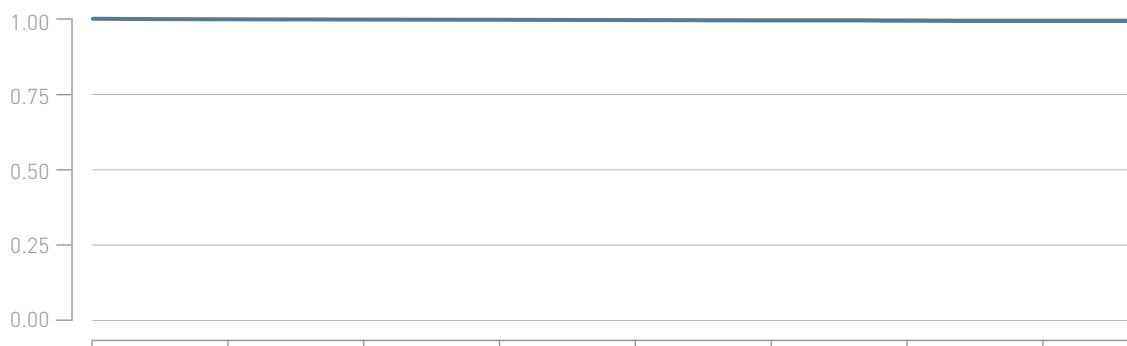
### Siello S/Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	1942 000
Registered U.S. Implants	182 775
Estimated Active U.S. Implants	174 000
U.S. Total Returned	809

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	696	0.38%	<b>U.S. Confirmed Malfunctions</b>	38	0.02%
Abnormal Pacing Impedance	45	0.02%	Conductor Fracture	16	0.01%
Cardiac Perforation	17	0.01%	Insulation Breach	17	0.01%
Conductor Fracture	19	0.01%	Other	5	0.00%
Extracardiac Stimulation	9	0.00%			
Failure to Capture	186	0.10%	<b>U.S. Acute Lead Observations</b>	357	0.19%
Failure to Sense	34	0.02%	Abnormal Pacing Impedance	4	0.00%
Insulation Breach	11	0.01%	Cardiac Perforation	31	0.02%
Lead Dislodgement	296	0.16%	Conductor Fracture	1	0.00%
Oversensing	57	0.03%	Failure to Capture	61	0.03%
Other	22	0.01%	Failure to Sense	8	0.00%
			Insulation Breach	3	0.00%
			Lead Dislodgement	219	0.12%
			Oversensing	9	0.00%
			Other	21	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.6	99.5	99.4	99.3	99.1	99.0
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.2	0.2
Sample Size	182775	144384	109745	70616	32735	2934	2391	1213

## 6.1 Pacing Leads

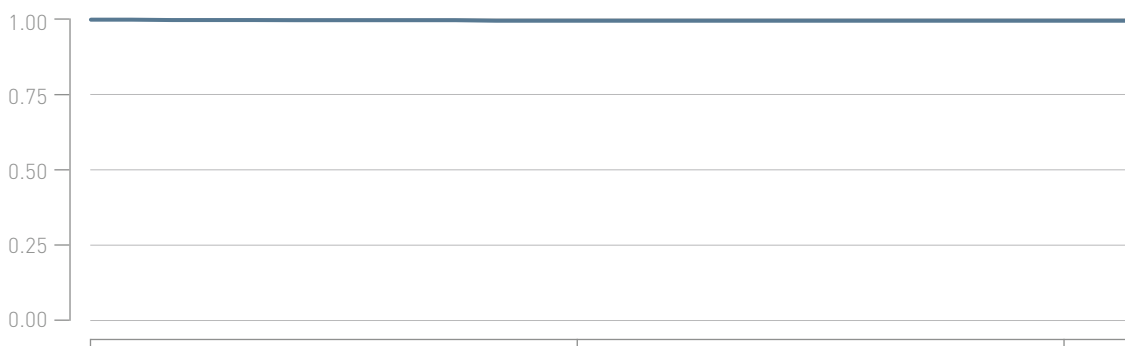
### Siello JT / Solia JT

Product Versions	42, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Okt 2009
Worldwide Distributed Devices	1 250 000
Registered U.S. Implants	1 593
Estimated Active U.S. Implants	1 500
U.S. Total Returned	9

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	8	0.50%	<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Failure to Capture	2	0.13%			
Failure to Sense	1	0.06%	<b>U.S. Acute Lead Observations</b>	10	0.63%
Insulation breach	1	0.06%	Failure to Capture	1	0.06%
Lead Dislodgement	4	0.25%	Lead Dislodgement	6	0.56%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2
Total [%]	100.0	99.4	99.4
CI [±%]	-	0.4	0.4
Sample Size	1593	940	315

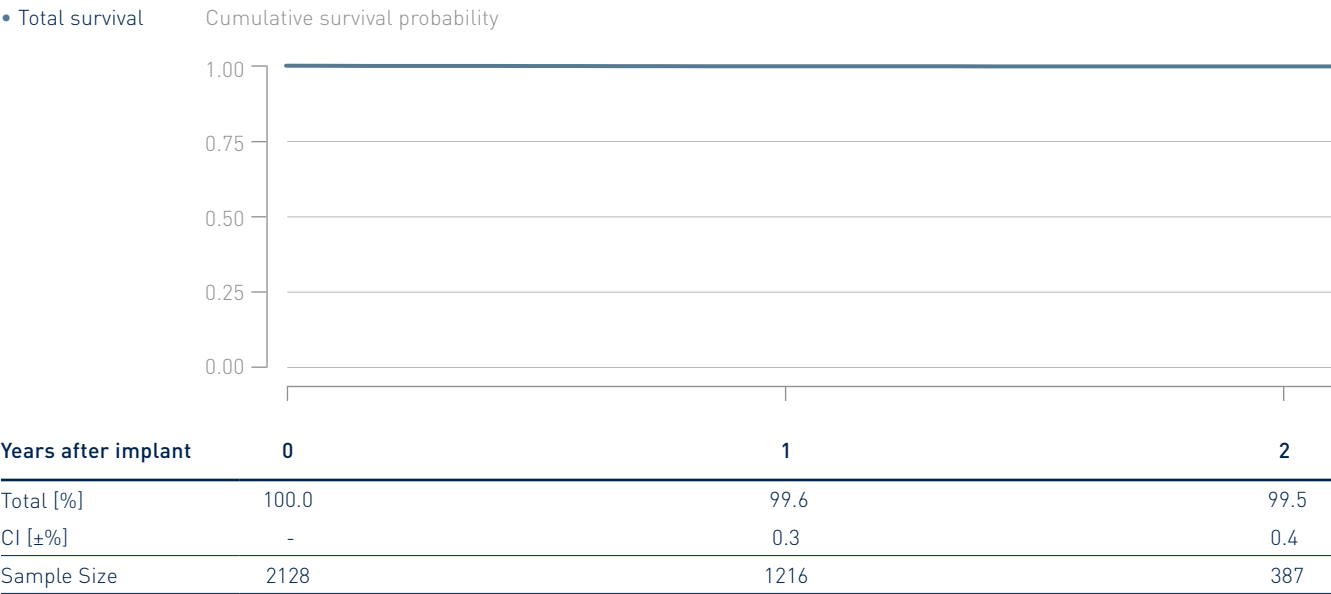


6.1 Pacing Leads

Siello T / Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Okt 2009
Worldwide Distributed Devices	196 000
Registered U.S. Implants	2 128
Estimated Active U.S. Implants	1990
U.S. Total Returned	7

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	7	0.33%	<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Abnormal Pacing Impedance	2	0.09%			
Failure to Capture	4	0.19%	<b>U.S. Acute Lead Observations</b>	9	0.42%
Lead Dislodgement	1	0.05%	Failure to Capture	3	0.14%
			Lead Dislodgement	6	0.28%



## 6.1 Pacing Leads

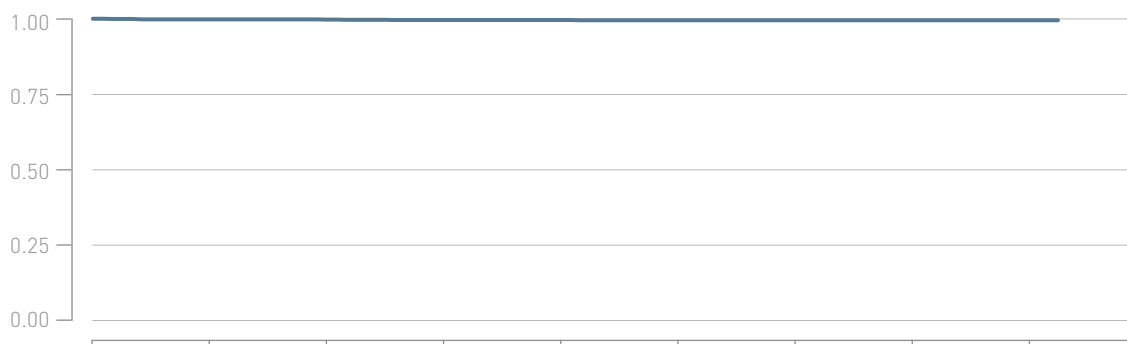
### Tilda JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2012
CE Market Release	Sep 2011
Worldwide Distributed Devices	17300
Registered U.S. Implants	1015
Estimated Active U.S. Implants	947
U.S. Total Returned	0

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	7	0.69%	<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Abnormal Pacing Impedance	2	0.20%			
Failure to Capture	2	0.20%	<b>U.S. Acute Lead Observations</b>	1	0.10%
Lead Dislodgement	3	0.30%	Lead Dislodgement	1	0.10%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3
CI [±%]	-	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1015	994	970	922	859	745	587	442	271

## 6.1 Pacing Leads

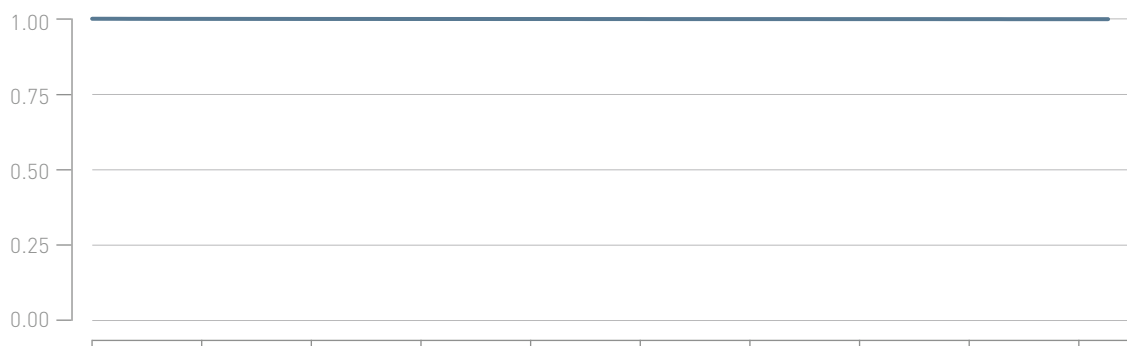
### Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41300
Registered U.S. Implants	12637
Estimated Active U.S. Implants	11800
U.S. Total Returned	16

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	36	0.28%	<b>U.S. Confirmed Malfunctions</b>	1	0.01%
Abnormal Pacing Impedance	1	0.01%	Conductor Fracture	1	0.01%
Conductor Fracture	6	0.05%			
Extracardiac Stimulation	1	0.01%	<b>U.S. Acute Lead Observations</b>	9	0.07%
Failure to Capture	8	0.06%	Failure to Capture	1	0.01%
Insulation Breach	2	0.02%	Lead Dislodgement	8	0.06%
Lead Dislodgement	9	0.07%			
Oversensing	5	0.04%			
Other	4	0.03%			

#### • Total survival

Cumulative survival probability



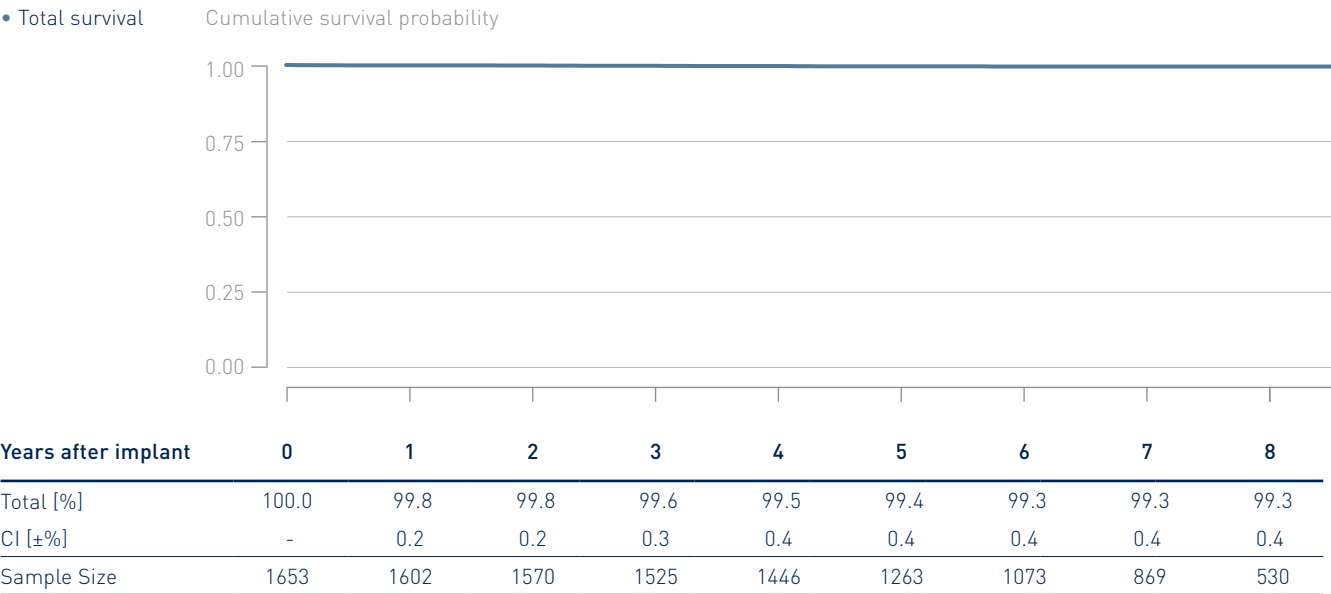
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7	99.6
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	12637	12279	12048	11556	10862	9366	7757	5999	3774	1091

6.1 Pacing Leads

Tilda T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22400
Registered U.S. Implants	1653
Estimated Active U.S. Implants	1510
U.S. Total Returned	2

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	11	0.67%	<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Abnormal Pacing Impedance	4	0.24%			
Conductor Fracture	2	0.12%	<b>U.S. Acute Lead Observations</b>	0	0.00%
Insulation Breach	1	0.06%			
Lead Dislodgement	4	0.24%			



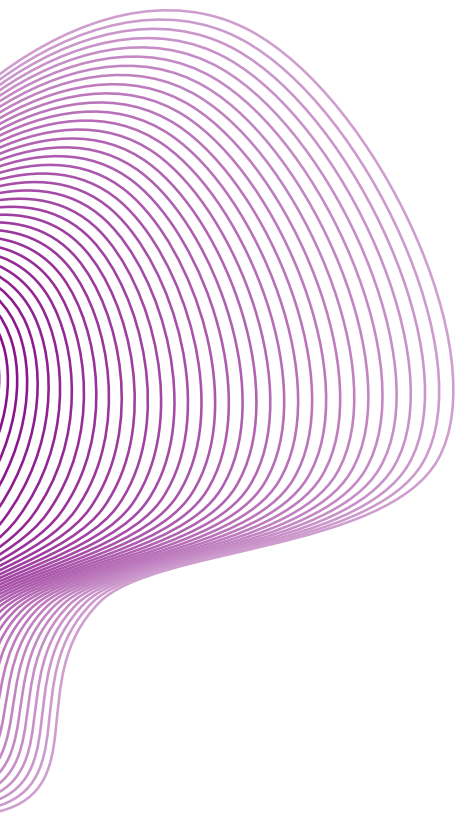
# Performance of **BIOTRONIK Leads**

Based on Returned Products  
and Complaint Data

6.1 Pacing Leads

**6.2 ICD Leads**

6.3 CRT Leads



## 6.2 ICD Leads

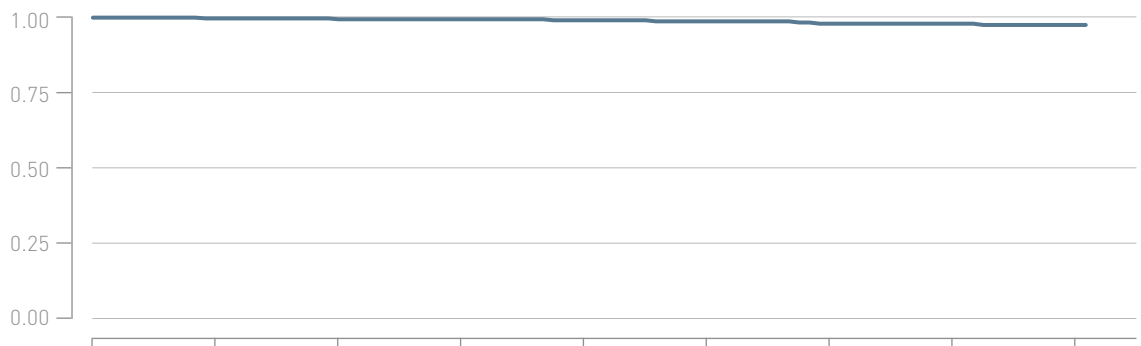
### Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5460
Registered U.S. Implants	406
Estimated Active U.S. Implants	171
U.S. Total Returned	8

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	10	2.46%	<b>U.S. Confirmed Malfunctions</b>	2	0.49%
Conductor Fracture	1	0.25%	Conductor Fracture	1	0.25%
Failure to Capture	4	0.98%	Insulation Breach	1	0.25%
Insulation Breach	1	0.25%	<b>U.S. Acute Lead Observations</b>	0	0.00%
Oversensing	4	0.98%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	99.4	99.0	98.6	97.8	97.8	97.3
CI [±%]	-	0.6	0.8	0.8	1.1	1.3	1.8	1.8	2
Sample Size	406	353	318	286	269	243	228	211	201

## 6.2 ICD Leads

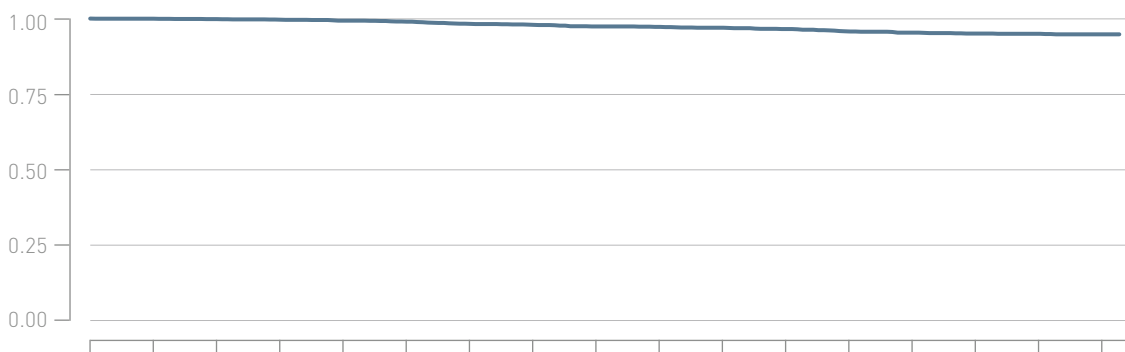
### Kentrox SL-S

Product Versions	65/16, 18 -Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8740
Registered U.S. Implants	2414
Estimated Active U.S. Implants	1210
U.S. Total Returned	42

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	66	2.72%	<b>U.S. Confirmed Malfunctions</b>	14	0.58%
Abnormal Defibrillation Impedance	1	0.04%	Insulation Breach	14	0.58%
Abnormal Pacing Impedance	5	0.21%			
Conductor Fracture	6	0.25%	<b>U.S. Acute Lead Observations</b>	2	0.08%
Failure to Capture	3	0.12%	Insulation Breach	1	0.04%
Failure to Sense	1	0.04%	Oversensing	1	0.04%
Insulation Breach	3	0.12%			
Lead Dislodgement	2	0.08%			
Oversensing	42	1.73%			
Other	3	0.12%			

#### • Total survival

Cumulative survival probability



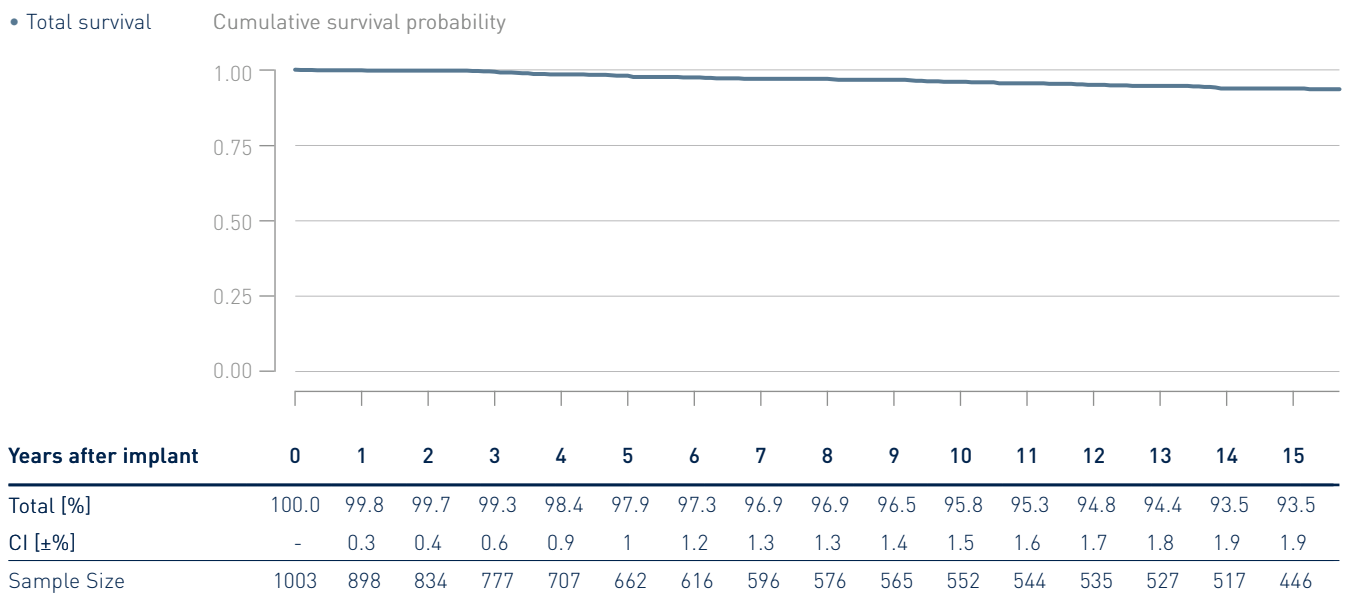
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	100.0	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.7	94.6
CI [±%]	-	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.1	1.2
Sample Size	2414	2176	2051	1891	1756	1632	1512	1432	1364	1325	1283	1260	1235	1220	1186	1095	401

## 6.2 ICD Leads

### Kentrox SL

Product Versions	65, 75, 100, -Steroid
Lead Type	dual coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Dec 2003 / Dec 2004
Worldwide Distributed Devices	8440
Registered U.S. Implants	1003
Estimated Active U.S. Implants	522
U.S. Total Returned	19

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	38	3.76%	<b>U.S. Confirmed Malfunctions</b>	5	0.49%
Abnormal Defibrillation Impedance	1	0.10%	Insulation Breach	5	0.49%
Abnormal Pacing Impedance	4	0.40%			
Conductor Fracture	3	0.30%	<b>U.S. Acute Lead Observations</b>	0	0.00%
Failure to Capture	4	0.40%			
Insulation Breach	6	0.59%			
Oversensing	18	1.78%			
Other	2	0.20%			





## 6.2 ICD Leads

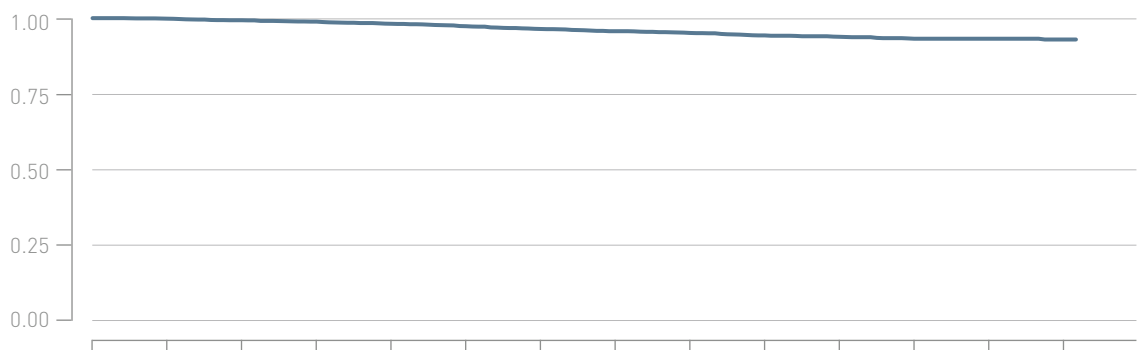
### Linux S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	2 466
Estimated Active U.S. Implants	1 630
U.S. Total Returned	86

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	85	3.41%	<b>U.S. Confirmed Malfunctions</b>	47	1.89%
Abnormal Defibrillation Impedance	8	0.32%	Conductor Fracture	8	0.32%
Abnormal Pacing Impedance	6	0.24%	Insulation Breach	39	1.56%
Conductor Fracture	8	0.32%			
Failure to Capture	10	0.40%	<b>U.S. Acute Lead Observations</b>	2	0.08%
Failure to Sense	1	0.04%	Lead Dislodgement	1	0.04%
Insulation Breach	4	0.16%	Other	1	0.04%
Oversensing	42	1.68%			
Other	6	0.24%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.8	99.3	98.8	98.1	97.2	96.3	95.5	94.9	94.0	93.6	92.9	92.9	92.6
CI [±%]	-	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1	1.1	1.2	1.2	1.3
Sample Size	2466	2261	2129	2017	1924	1848	1784	1741	1695	1650	1473	903	511	265

## 6.2 ICD Leads

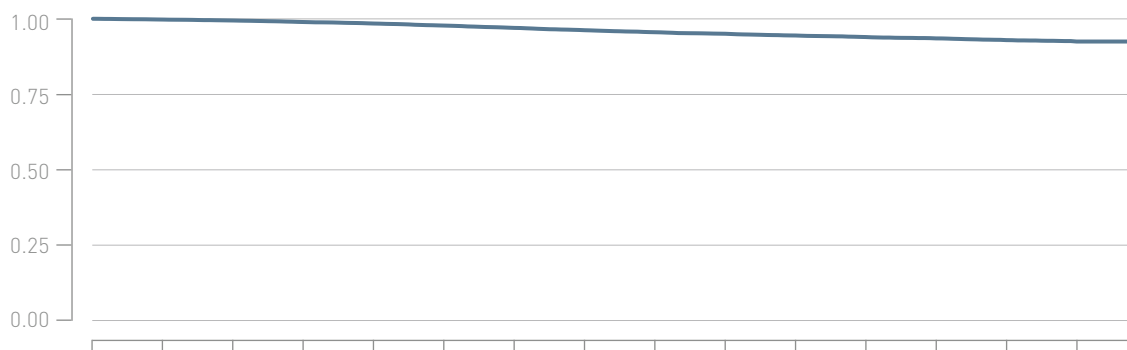
### Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	22 094
Estimated Active U.S. Implants	14 100
U.S. Total Returned	526

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	897	4.03%	<b>U.S. Confirmed Malfunctions</b>	218	0.98%
Abnormal Defibrillation Impedance	80	0.36%	Conductor Fracture	31	0.14%
Abnormal Pacing Impedance	64	0.29%	Insulation Breach	185	0.83%
Cardiac Perforation	3	0.01%	Other	2	0.01%
Conductor Fracture	103	0.46%			
Failure to Capture	76	0.34%	<b>U.S. Acute Lead Observations</b>	11	0.05%
Failure to Sense	18	0.08%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	61	0.27%	Cardiac Perforation	1	0.00%
Lead Dislodgement	31	0.14%	Failure to Capture	1	0.00%
Oversensing	414	1.86%	Lead Dislodgement	6	0.03%
Other	47	0.21%	Oversensing	1	0.00%
			Other	1	0.00%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.8	93.3	92.7	92.2
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5
Sample Size	22094	20084	18845	17789	16941	16203	15602	15149	14778	14530	13989	10936	7219	4034	1728

## 6.2 ICD Leads

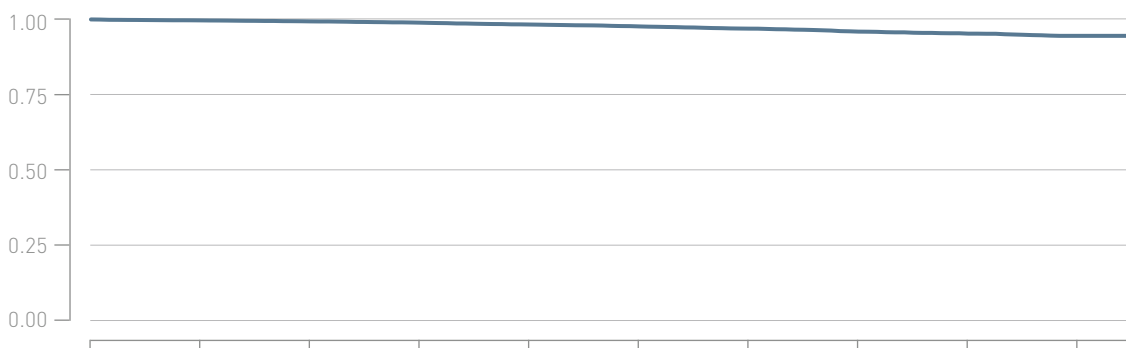
### Linux<sup>smart</sup> S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	7 599
Estimated Active U.S. Implants	6 110
U.S. Total Returned	195

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	225	2.94%	<b>U.S. Confirmed Malfunctions</b>	76	0.99%
Abnormal Defibrillation Impedance	15	0.20%	Conductor Fracture	12	0.16%
Abnormal Pacing Impedance	21	0.27%	Insulation Breach	64	0.84%
Cardiac Perforation	1	0.01%	<b>U.S. Acute Lead Observations</b>	10	0.13%
Conductor Fracture	26	0.34%	Abnormal Pacing Impedance	1	0.01%
Failure to Capture	24	0.31%	Cardiac Perforation	1	0.01%
Failure to Sense	11	0.14%	Lead Dislodgement	7	0.09%
Insulation Breach	5	0.07%	Other	1	0.01%
Lead Dislodgement	14	0.18%			
Oversensing	99	1.29%			
Other	9	0.12%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.3	98.9	98.2	97.6	96.8	95.8	95.1	94.3
CI [±%]	-	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.6	0.7
Sample Size	7599	7135	6873	6674	6451	6092	5503	4307	2758	1082

## 6.2 ICD Leads

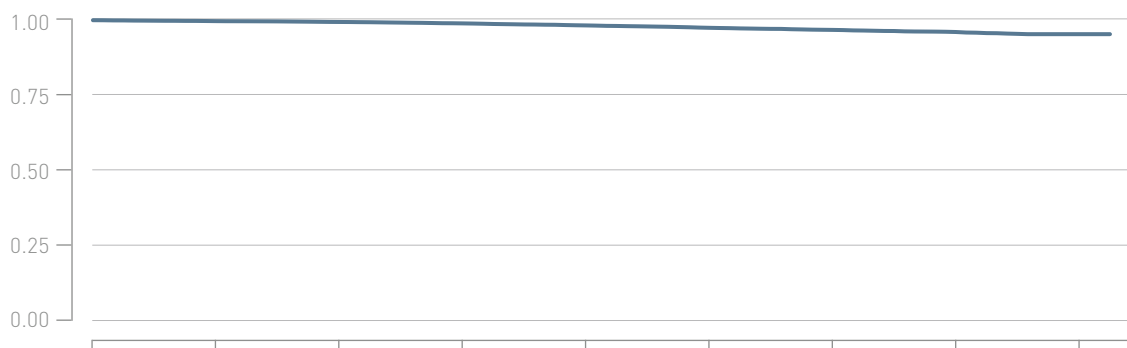
### Linux<sup>smart</sup> S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	16305
Estimated Active U.S. Implants	14300
U.S. Total Returned	361

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	384	2.34%	<b>U.S. Confirmed Malfunctions</b>	108	0.66%
Abnormal Defibrillation Impedance	43	0.26%	Conductor Fracture	9	0.05%
Abnormal Pacing Impedance	27	0.16%	Insulation Breach	99	0.60%
Conductor Fracture	42	0.26%			
Failure to Capture	34	0.21%	<b>U.S. Acute Lead Observations</b>	39	0.24%
Failure to Sense	16	0.10%	Cardiac Perforation	4	0.02%
Insulation Breach	6	0.04%	Failure to Capture	9	0.05%
Lead Dislodgement	47	0.29%	Lead Dislodgement	16	0.10%
Oversensing	161	0.98%	Oversensing	3	0.02%
Other	8	0.05%	Other	7	0.04%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	98.9	98.2	97.3	96.6	95.9	95.1
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.5
Sample Size	16305	15519	15207	14777	13745	10019	6607	3464	728

## 6.2 ICD Leads

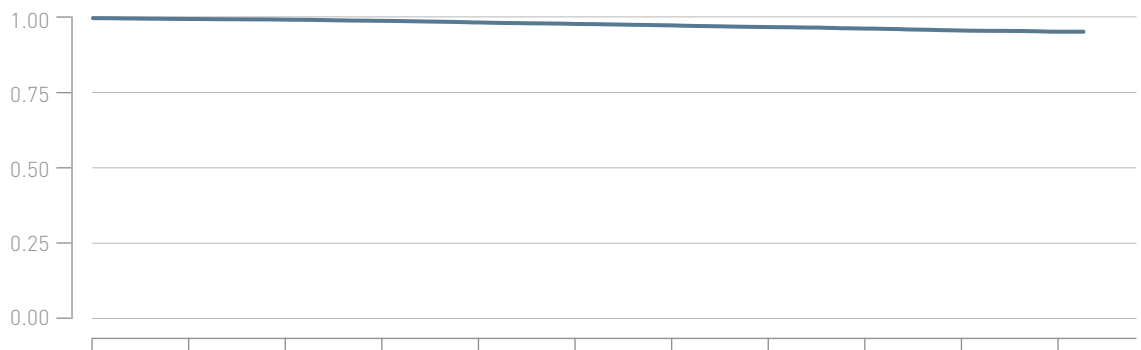
### Linux<sup>smart</sup> SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	13 130
Estimated Active U.S. Implants	10 500
U.S. Total Returned	262

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	364	2.75%	<b>U.S. Confirmed Malfunctions</b>	78	0.59%
Abnormal Defibrillation Impedance	36	0.27%	Conductor Fracture	10	0.08%
Abnormal Pacing Impedance	24	0.18%	Insulation Breach	66	0.50%
Cardiac Perforation	1	0.01%	Other	2	0.02%
Conductor Fracture	46	0.35%			
Extracardiac Stimulation	1	0.01%	<b>U.S. Acute Lead Observations</b>	29	0.22%
Failure to Capture	30	0.23%	Abnormal Defibrillation Impedance	1	0.01%
Failure to Sense	11	0.08%	Cardiac Perforation	2	0.02%
Insulation Breach	9	0.07%	Failure to Capture	4	0.03%
Lead Dislodgement	25	0.19%	Insulation Breach	1	0.01%
Oversensing	173	1.31%	Lead Dislodgement	12	0.09%
Other	8	0.06%	Oversensing	2	0.02%
			Other	7	0.05%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.5	99.1	98.5	98.0	97.5	96.9	96.3	95.6	95.2
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.5
Sample Size	13130	12177	11792	11429	11082	10628	10061	8997	7169	4231	925

## 6.2 ICD Leads

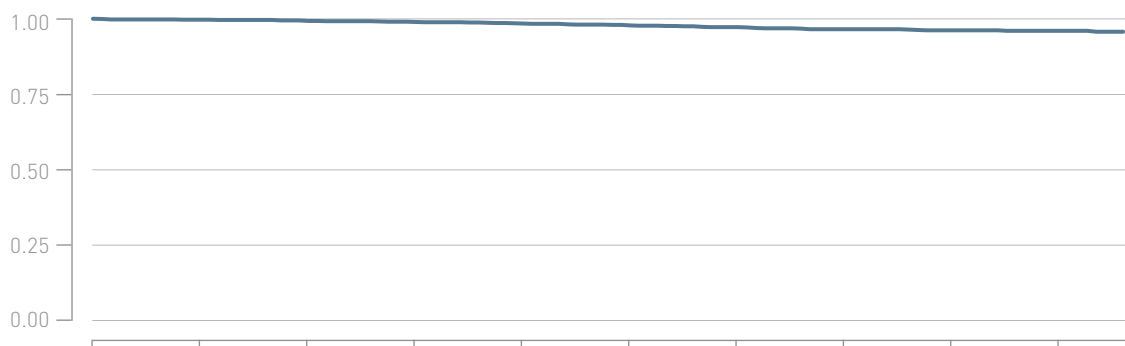
### Linux<sup>smart</sup> TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7720
Registered U.S. Implants	1265
Estimated Active U.S. Implants	994
U.S. Total Returned	22

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	44	3.45%	<b>U.S. Confirmed Malfunctions</b>	1	0.08%
Abnormal Defibrillation Impedance	7	0.55%	Insulation Breach	1	0.08%
Abnormal Pacing Impedance	5	0.39%			
Conductor Fracture	3	0.24%	<b>U.S. Acute Lead Observations</b>	3	0.24%
Failure to Capture	9	0.71%	Lead Dislodgement	3	0.24%
Insulation Breach	2	0.16%			
Lead Dislodgement	4	0.31%			
Oversensing	13	1.02%			
Other	1	0.08%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.2	98.9	98.3	97.7	97.1	96.4	96.0	95.8
CI [±%]	-	0.3	0.5	0.6	0.7	0.9	1	1.1	1.2	1.2
Sample Size	1265	1174	1138	1096	1070	1025	966	869	695	386

## 6.2 ICD Leads

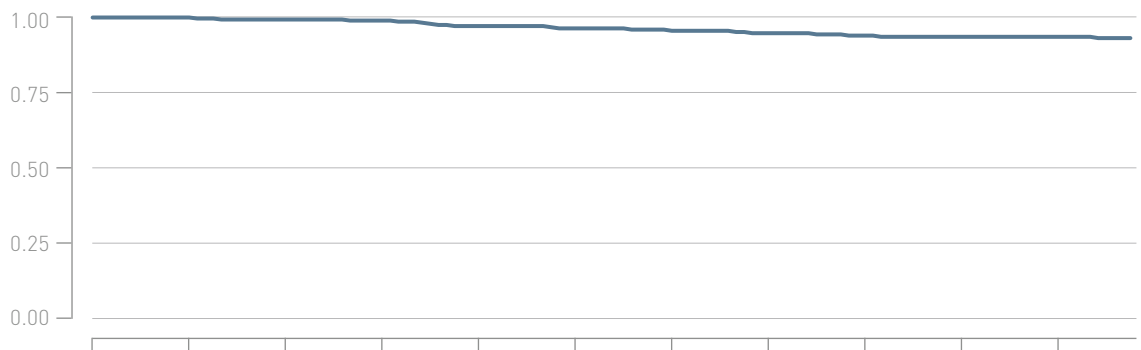
### Linux T

Product Versions	65, 75
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	2260
Registered U.S. Implants	319
Estimated Active U.S. Implants	217
U.S. Total Returned	4

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	19	5.90%	<b>U.S. Confirmed Malfunctions</b>	3	0.93%
Abnormal Pacing Impedance	3	0.93%	Conductor Fracture	1	0.31%
Conductor Fracture	1	0.31%	Insulation Breach	2	0.62%
Failure to Capture	4	1.24%			
Insulation Breach	1	0.31%	<b>U.S. Acute Lead Observations</b>	1	0.31%
Oversensing	9	2.80%	Other	1	0.31%
Other	1	0.31%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4	93.4
CI [±%]	-	< 0.1	0.9	1.2	2	2.3	2.5	2.7	2.9	3	3
Sample Size	319	295	283	272	251	241	234	230	228	226	221

## 6.2 ICD Leads

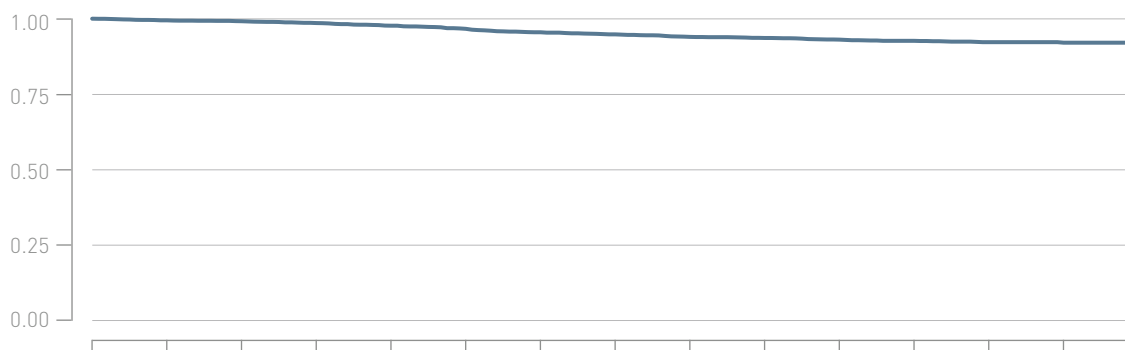
### Linux TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered U.S. Implants	3 021
Estimated Active U.S. Implants	1 980
U.S. Total Returned	81

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	146	4.79%	<b>U.S. Confirmed Malfunctions</b>	38	1.25%
Abnormal Defibrillation Impedance	15	0.49%	Conductor Fracture	6	0.20%
Abnormal Pacing Impedance	14	0.46%	Insulation Breach	32	1.05%
Cardiac Perforation	1	0.03%	<b>U.S. Acute Lead Observations</b>	3	0.10%
Conductor Fracture	18	0.59%	Failure to Capture	1	0.03%
Failure to Capture	24	0.79%	Lead Dislodgement	2	0.07%
Failure to Sense	4	0.13%			
Insulation Breach	13	0.43%			
Lead Dislodgement	4	0.13%			
Oversensing	50	1.64%			
Other	3	0.10%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.4	94.6	93.8	93.4	92.8	92.4	92.0	91.8
CI [±%]	-	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1	1	1	1.1	1.1	1.2
Sample Size	3021	2730	2598	2451	2338	2235	2145	2091	2047	2021	1911	1524	975	500



## 6.2 ICD Leads

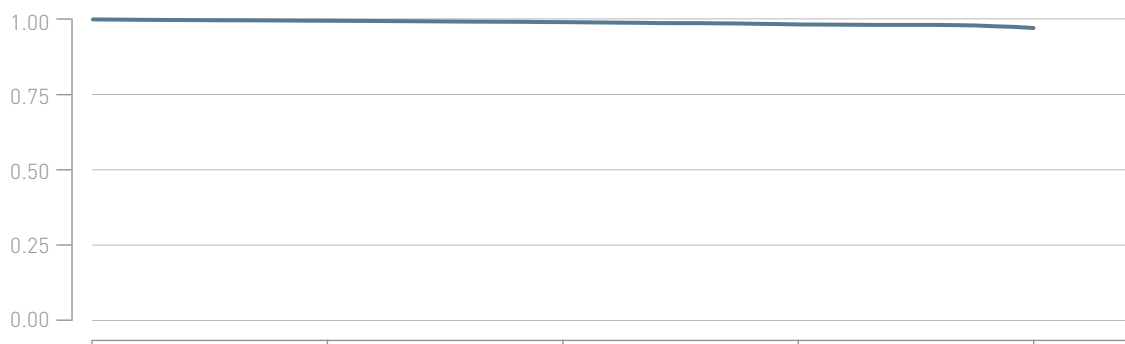
### Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	95600
Registered U.S. Implants	14632
Estimated Active U.S. Implants	13800
U.S. Total Returned	127

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	129	0.88%	<b>U.S. Confirmed Malfunctions</b>	24	0.16%
Abnormal Defibrillation Impedance	13	0.09%	Conductor Fracture	5	0.03%
Abnormal Pacing Impedance	2	0.01%	Insulation Breach	18	0.12%
Cardiac Perforation	1	0.01%			
Conductor Fracture	7	0.05%	<b>U.S. Acute Lead Observations</b>	32	0.22%
Failure to Capture	16	0.11%	Abnormal Pacing Impedance	2	0.01%
Failure to Sense	7	0.05%	Cardiac Perforation	5	0.03%
Insulation Breach	1	0.01%	Failure to Capture	8	0.05%
Lead Dislodgement	22	0.15%	Lead Dislodgement	16	0.11%
Oversensing	53	0.36%	Oversensing	1	0.01%
Other	7	0.05%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.0	98.2	96.9
CI [±%]	-	0.1	0.2	0.3	1.1
Sample Size	14632	10703	6975	3349	249

## 6.2 ICD Leads

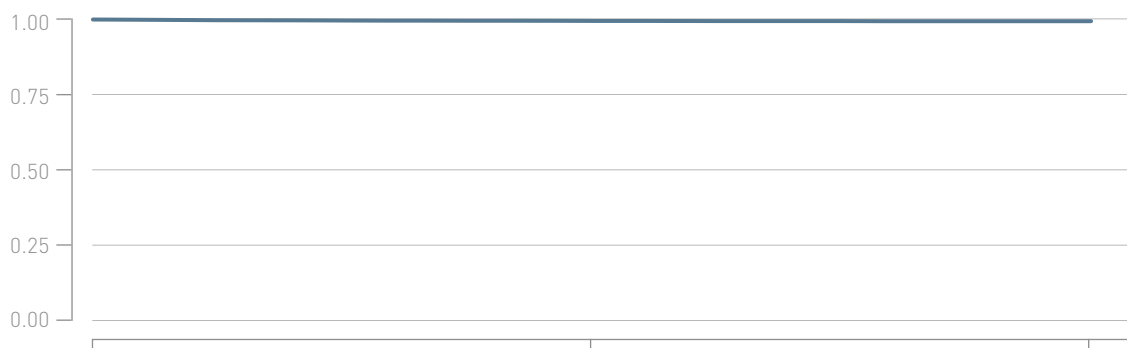
### Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	18700
Registered U.S. Implants	7706
Estimated Active U.S. Implants	7410
U.S. Total Returned	56

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	37	0.48%	<b>U.S. Confirmed Malfunctions</b>	5	0.06%
Abnormal Defibrillation Impedance	2	0.03%	Conductor Fracture	1	0.01%
Abnormal Pacing Impedance	1	0.01%	Insulation Breach	4	0.05%
Cardiac Perforation	1	0.01%			
Failure to Capture	6	0.08%	<b>U.S. Acute Lead Observations</b>	26	0.34%
Failure to Sense	2	0.03%	Failure to Capture	8	0.10%
Lead Dislodgement	15	0.19%	Failure to Sense	4	0.05%
Oversensing	10	0.13%	Lead Dislodgement	10	0.13%
			Oversensing	3	0.04%
			Other	1	0.01%

#### • Total survival

Cumulative survival probability



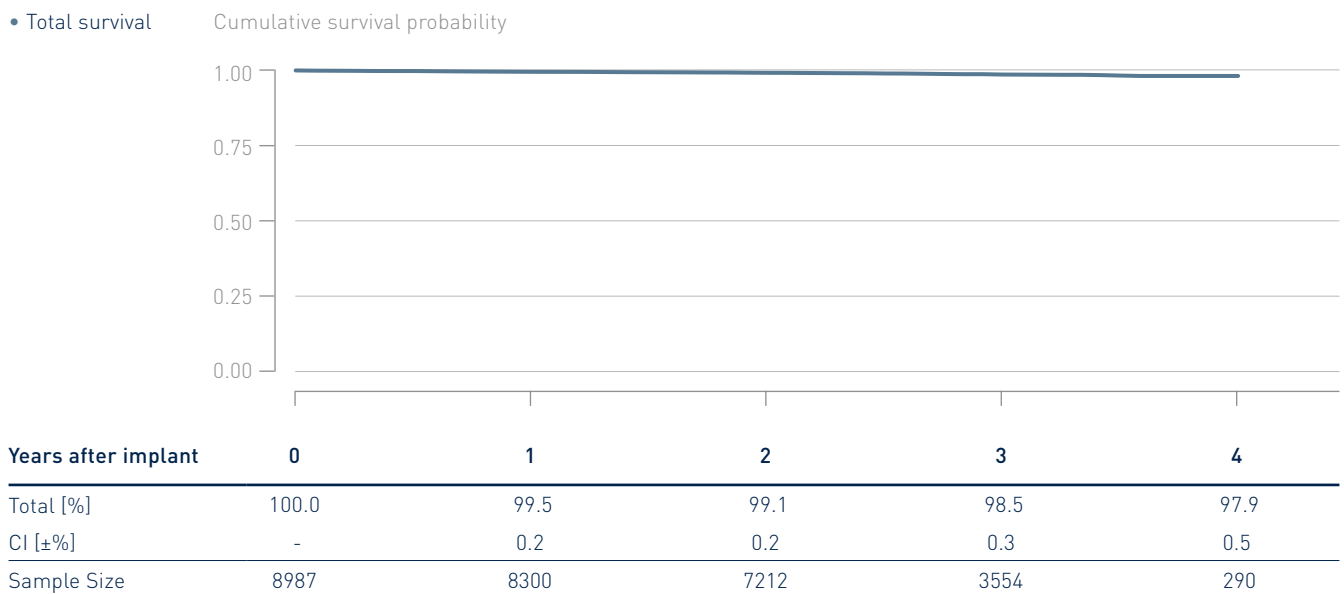
Years after implant	0	1	2
Total [%]	100.0	99.3	99.2
CI [±%]	-	0.2	0.3
Sample Size	7706	3466	352

## 6.2 ICD Leads

### Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	20 600
Registered U.S. Implants	8 987
Estimated Active U.S. Implants	8 390
U.S. Total Returned	113

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	88	0.97%	<b>U.S. Confirmed Malfunctions</b>	28	0.31%
Abnormal Defibrillation Impedance	13	0.14%	Conductor Fracture	2	0.02%
Abnormal Pacing Impedance	1	0.01%	Insulation Breach	26	0.29%
Conductor Fracture	1	0.01%			
Failure to Capture	7	0.08%	<b>U.S. Acute Lead Observations</b>	20	0.22%
Failure to Sense	7	0.08%	Cardiac Perforation	2	0.02%
Insulation Breach	2	0.02%	Failure to Capture	2	0.02%
Lead Dislodgement	18	0.20%	Failure to Sense	1	0.01%
Oversensing	39	0.43%	Lead Dislodgement	12	0.13%
			Oversensing	1	0.01%
			Other	2	0.02%



## 6.2 ICD Leads

### Plexa SD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	12 100
Registered U.S. Implants	3 981
Estimated Active U.S. Implants	3 740
U.S. Total Returned	19

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	35	0.87%	<b>U.S. Confirmed Malfunctions</b>	2	0.05%
Abnormal Defibrillation Impedance	4	0.10%	Conductor Fracture	1	0.02%
Abnormal Pacing Impedance	1	0.02%	Insulation Breach	1	0.02%
Conductor Fracture	1	0.02%			
Extracardiac Stimulation	1	0.02%	<b>U.S. Acute Lead Observations</b>	11	0.27%
Failure to Capture	2	0.05%	Abnormal Defibrillation Impedance	2	0.05%
Failure to Sense	2	0.05%	Abnormal Pacing Impedance	1	0.02%
Insulation Breach	2	0.05%	Cardiac Perforation	2	0.05%
Lead Dislodgement	7	0.17%	Failure to Capture	2	0.05%
Oversensing	13	0.32%	Lead Dislodgement	1	0.02%
Other	2	0.05%	Oversensing	2	0.05%
			Other	1	0.02%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	99.5	99.1	98.7
CI [±%]	-	0.2	0.4	0.5
Sample Size	3 981	2 968	2 020	934

## 6.2 ICD Leads

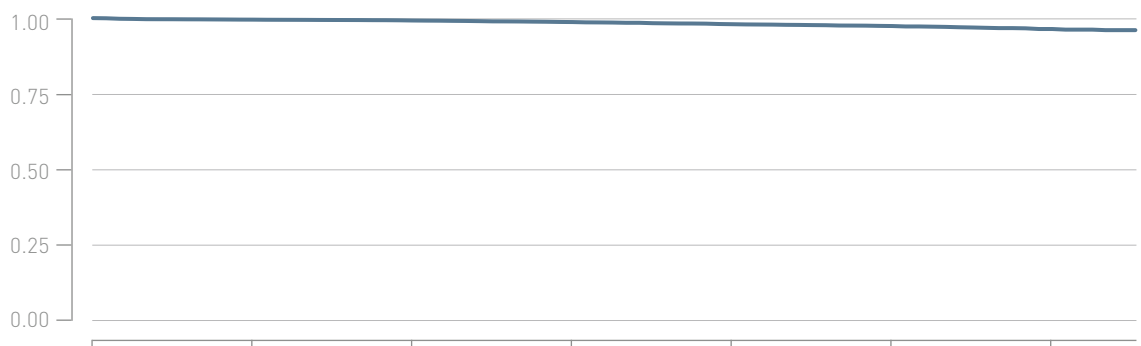
### Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	8 279
Estimated Active U.S. Implants	7 170
U.S. Total Returned	123

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	167	2.00%	<b>U.S. Confirmed Malfunctions</b>	50	0.60%
Abnormal Defibrillation Impedance	8	0.10%	Conductor Fracture	8	0.10%
Abnormal Pacing Impedance	7	0.08%	Insulation Breach	41	0.49%
Cardiac Perforation	1	0.01%	Other	1	0.01%
Conductor Fracture	14	0.17%			
Extracardiac Stimulation	2	0.02%	<b>U.S. Acute Lead Observations</b>	28	0.34%
Failure to Capture	20	0.24%	Cardiac Perforation	2	0.02%
Failure to Sense	4	0.05%	Extracardiac Stimulation	1	0.01%
Insulation Breach	3	0.04%	Failure to Capture	3	0.04%
Lead Dislodgement	24	0.29%	Lead Dislodgement	13	0.16%
Oversensing	79	0.95%	Other	9	0.11%
Other	5	0.06%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.5	99.2	98.6	97.9	97.2	96.2
CI [±%]	-	0.2	0.2	0.3	0.3	0.4	0.6
Sample Size	8 279	7 789	7 594	7 274	6 419	3 514	1 049

## 6.2 ICD Leads

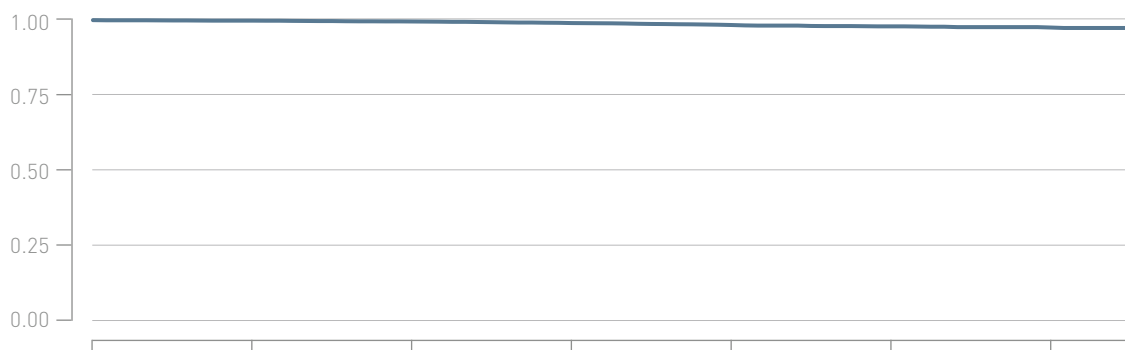
### Protego SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18400
Registered U.S. Implants	3411
Estimated Active U.S. Implants	3010
U.S. Total Returned	41

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	61	1.77%	<b>U.S. Confirmed Malfunctions</b>	12	0.35%
Abnormal Defibrillation Impedance	6	0.17%	Conductor Fracture	1	0.03%
Abnormal Pacing Impedance	2	0.06%	Insulation Breach	11	0.32%
Conductor Fracture	7	0.20%			
Failure to Capture	8	0.23%	<b>U.S. Acute Lead Observations</b>	3	0.09%
Failure to Sense	2	0.06%	Lead Dislodgement	2	0.06%
Insulation Breach	1	0.03%	Other	1	0.03%
Lead Dislodgement	4	0.12%			
Oversensing	29	0.84%			
Other	2	0.06%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.5	98.9	98.2	97.7	97.3
CI [±%]	-	0.1	0.2	0.4	0.5	0.5	0.7
Sample Size	3411	3235	3158	3093	2784	1793	669

## 6.2 ICD Leads

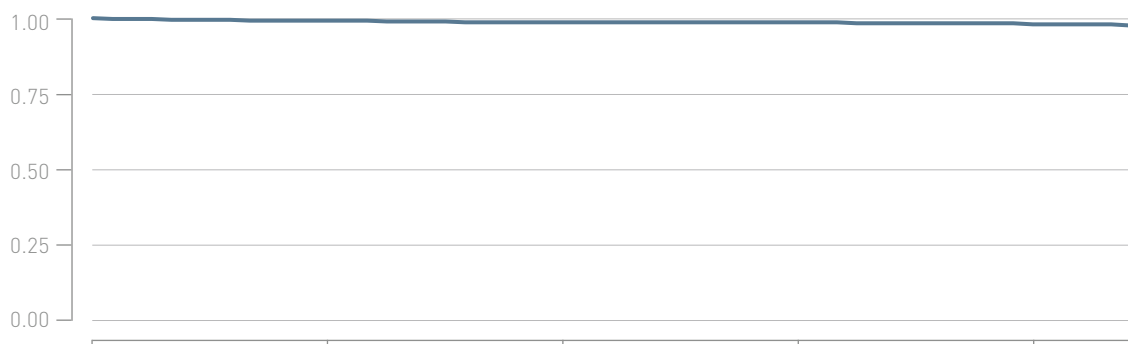
### Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1450
Registered U.S. Implants	349
Estimated Active U.S. Implants	306
U.S. Total Returned	4

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	9	2.56%	<b>U.S. Confirmed Malfunctions</b>	0	0.00%
Conductor Fracture	4	1.14%			
Failure to Capture	2	0.57%	<b>U.S. Acute Lead Observations</b>	0	0.00%
Failure to Sense	1	0.28%			
Insulation Breach	1	0.28%			
Other	1	0.28%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.1	98.5	98.5	97.8
CI [±%]	-	1	1.3	1.3	1.6
Sample Size	349	331	322	294	255

## 6.2 ICD Leads

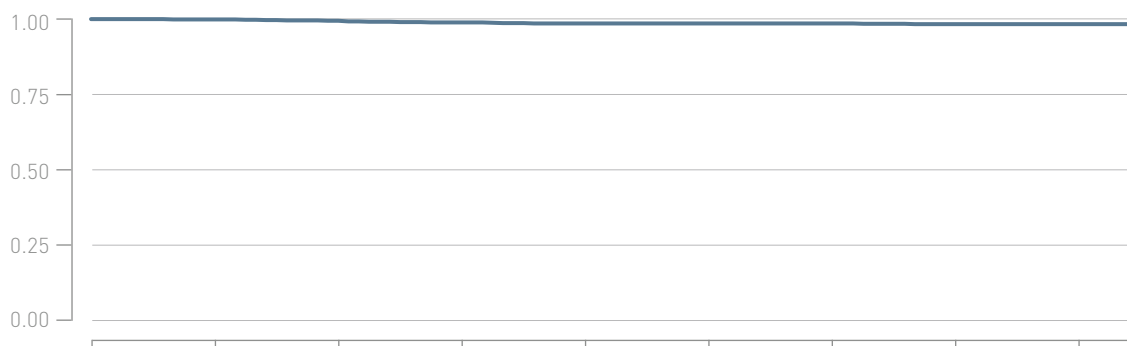
### Vigila 2CR

Product Versions	60/16, 65/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2012
CE Market Release	Oct 2011
Worldwide Distributed Devices	2730
Registered U.S. Implants	853
Estimated Active U.S. Implants	739
U.S. Total Returned	12

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	11	1.28%	<b>U.S. Confirmed Malfunctions</b>	4	0.47%
Abnormal Pacing Impedance	1	0.12%	Insulation Breach	4	0.47%
Conductor Fracture	1	0.12%			
Lead Dislodgement	3	0.35%	<b>U.S. Acute Lead Observations</b>	0	0.00%
Oversensing	6	0.70%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.9	99.4	98.8	98.4	98.4	98.4	98.1	98.1
CI [±%]	-	0.2	0.5	0.8	0.9	0.9	0.9	1	1
Sample Size	853	815	795	774	758	754	749	725	515



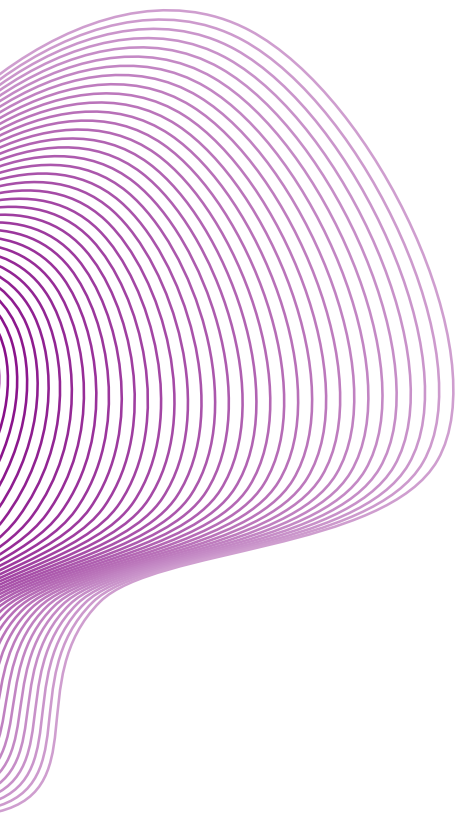
# Performance of **BIOTRONIK Leads**

Based on Returned Products  
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

**6.3 CRT Leads**



## 6.3 CRT Leads

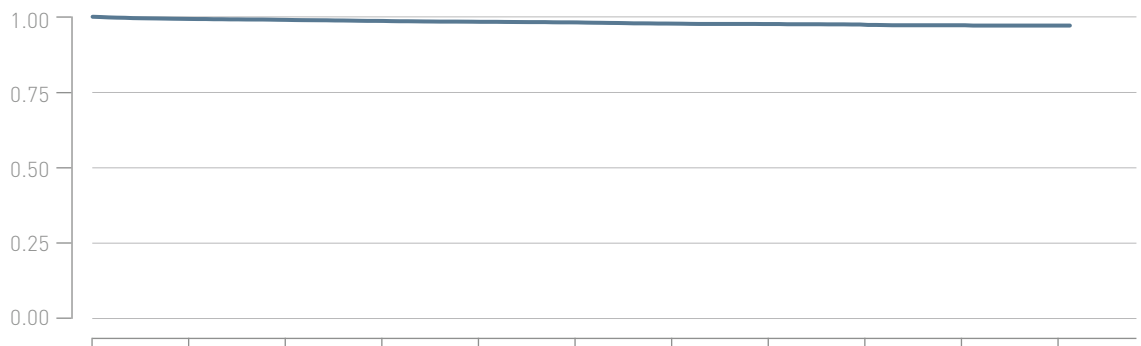
### Corox OTW-L BP

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Registered U.S. Implants	6 252
Estimated Active U.S. Implants	4 930
U.S. Total Returned	80

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	141	2.24%	<b>U.S. Confirmed Malfunctions</b>	4	0.06%
Abnormal Pacing Impedance	4	0.06%	Conductor Fracture	3	0.05%
Conductor Fracture	5	0.08%	Insulation Breach	1	0.02%
Extracardiac Stimulation	22	0.35%			
Failure to Capture	58	0.92%	<b>U.S. Acute Lead Observations</b>	21	0.33%
Failure to Sense	2	0.03%	Extracardiac Stimulation	6	0.10%
Insulation Breach	2	0.03%	Failure to Capture	2	0.03%
Lead Dislodgement	38	0.60%	Lead Dislodgement	10	0.16%
Oversensing	2	0.05%	Other	3	0.05%
Other	7	0.11%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.2	98.9	98.5	98.2	98.0	97.6	97.4	97.1	97.0	96.9
CI [±%]	-	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.6
Sample Size	6252	5695	5450	5253	5091	4398	3675	2805	1862	940	264

## 6.3 CRT Leads

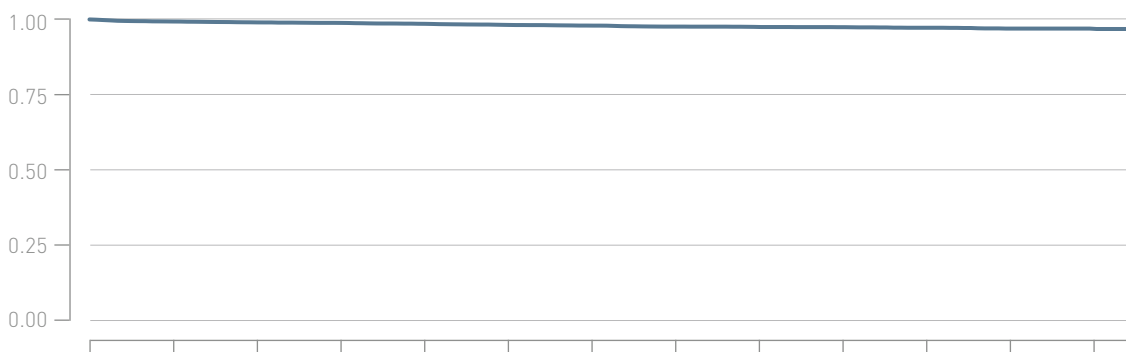
### Corox OTW-S BP

Product Versions _____	75, 85
Lead Type _____	thread fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	26 400
Registered U.S. Implants _____	8 158
Estimated Active U.S. Implants _____	5 680
U.S. Total Returned _____	131

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b> _____	174	2.12%	<b>U.S. Confirmed Malfunctions</b> _____	13	0.16%
Abnormal Pacing Impedance _____	10	0.12%	Conductor Fracture _____	8	0.10%
Conductor Fracture _____	5	0.06%	Insulation Breach _____	4	0.05%
Extracardiac Stimulation _____	15	0.18%	Other _____	1	0.01%
Failure to Capture _____	53	0.64%			
Failure to Sense _____	1	0.01%	<b>U.S. Acute Lead Observations</b> _____	33	0.40%
Insulation Breach _____	4	0.05%	Cardiac Perforation _____	1	0.01%
Lead Dislodgement _____	60	0.73%	Extracardiac Stimulation _____	5	0.06%
Oversensing _____	6	0.07%	Failure to Capture _____	6	0.07%
Other _____	20	0.24%	Lead Dislodgement _____	20	0.24%
			Other _____	1	0.01%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.3	98.9	98.8	98.4	98.0	97.8	97.5	97.3	97.2	97.0	96.7	96.6
CI [±%]	-	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.6
Sample Size	8158	7168	6766	6434	6185	5606	5038	4359	3715	3106	2482	1526	649

## 6.3 CRT Leads

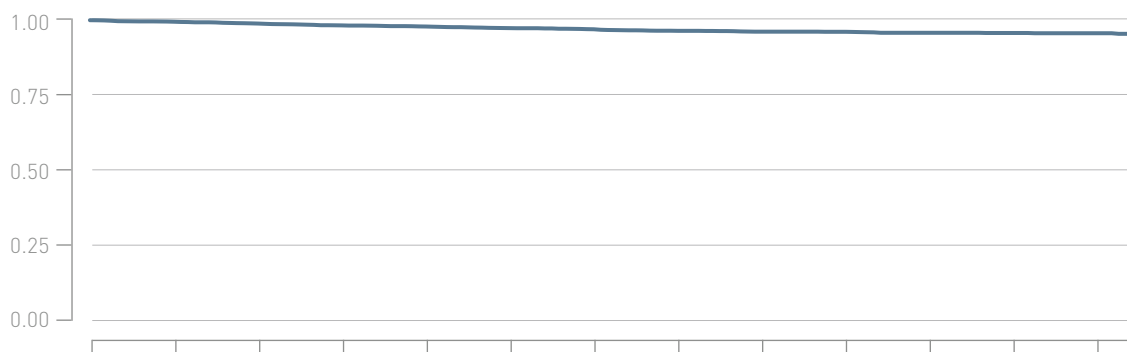
### Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered U.S. Implants	4 116
Estimated Active U.S. Implants	2 660
U.S. Total Returned	79

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	120	2.90%	<b>U.S. Confirmed Malfunctions</b>	16	0.39%
Abnormal Pacing Impedance	7	0.17%	Conductor Fracture	15	0.36%
Conductor Fracture	3	0.07%	Insulation Breach	1	0.02%
Extracardiac Stimulation	8	0.19%			
Failure to Capture	44	1.06%	<b>U.S. Acute Lead Observations</b>	9	0.22%
Insulation Breach	3	0.07%	Lead Dislodgement	7	0.17%
Lead Dislodgement	38	0.92%	Other	2	0.05%
Oversensing	5	0.12%			
Other	12	0.29%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.5	98.8	98.2	97.8	97.2	96.8	96.3	96.0	95.9	95.6	95.5	95.4
CI [±%]	-	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.8	0.8
Sample Size	4116	3556	3312	3118	2997	2827	2662	2479	2249	2018	1744	1265	591

## 6.3 CRT Leads

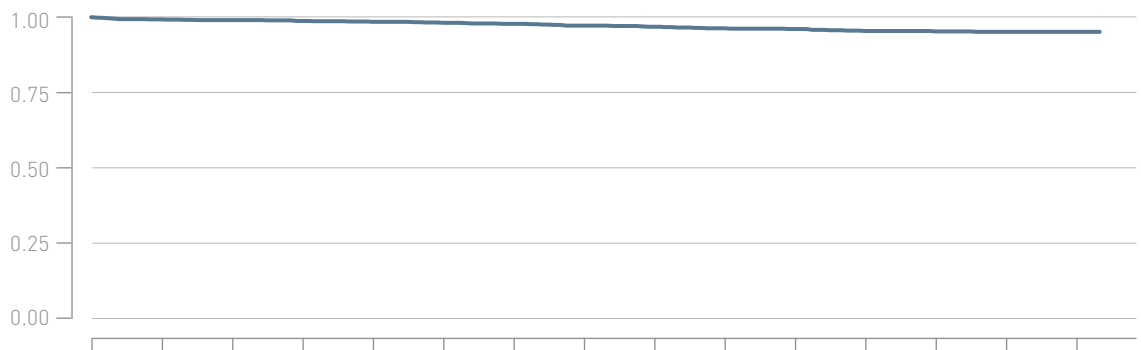
### Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10400
Registered U.S. Implants	1423
Estimated Active U.S. Implants	696
U.S. Total Returned	26

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	44	3.09%	<b>U.S. Confirmed Malfunctions</b>	2	0.14%
Abnormal Pacing Impedance	1	0.07%	Insulation Breach	2	0.14%
Conductor Fracture	2	0.14%			
Extracardiac Stimulation	7	0.49%	<b>U.S. Acute Lead Observations</b>	4	0.28%
Failure to Capture	16	1.12%	Failure to Capture	3	0.21%
Insulation Breach	2	0.14%	Lead Dislodgement	1	0.07%
Lead Dislodgement	10	0.70%			
Oversensing	1	0.07%			
Other	5	0.35%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.2	95.9	95.3	95.1	95.0	95.0
CI [±%]	-	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.4	1.4	1.4
Sample Size	1423	1237	1121	1016	932	865	810	776	746	729	712	704	696	669	337

## 6.3 CRT Leads

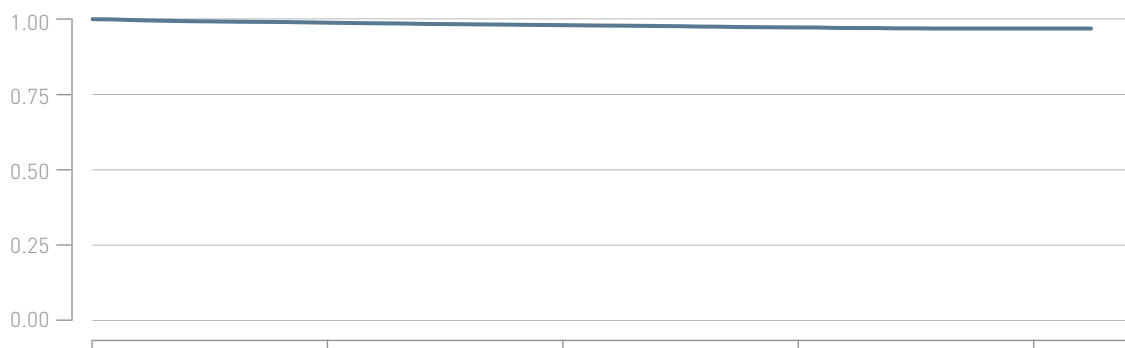
### Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	95800
Registered U.S. Implants	14253
Estimated Active U.S. Implants	12700
U.S. Total Returned	154

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	235	1.63%	<b>U.S. Confirmed Malfunctions</b>	33	0.23%
Abnormal Pacing Impedance	29	0.20%	Conductor Fracture	32	0.22%
Conductor Fracture	5	0.03%	Other	1	0.01%
Extracardiac Stimulation	14	0.10%			
Failure to Capture	53	0.37%	<b>U.S. Acute Lead Observations</b>	45	0.31%
Failure to Sense	2	0.01%	Abnormal Pacing Impedance	1	0.01%
Lead Dislodgement	92	0.64%	Conductor Fracture	1	0.01%
Oversensing	29	0.20%	Extracardiac Stimulation	7	0.05%
Other	11	0.08%	Failure to Capture	8	0.06%
			Lead Dislodgement	25	0.17%
			Oversensing	2	0.01%
			Other	1	0.01%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	98.8	97.9	97.1	96.7
CI [±%]	-	0.2	0.3	0.4	0.5
Sample Size	14253	9822	6532	3171	423

## 6.3 CRT Leads

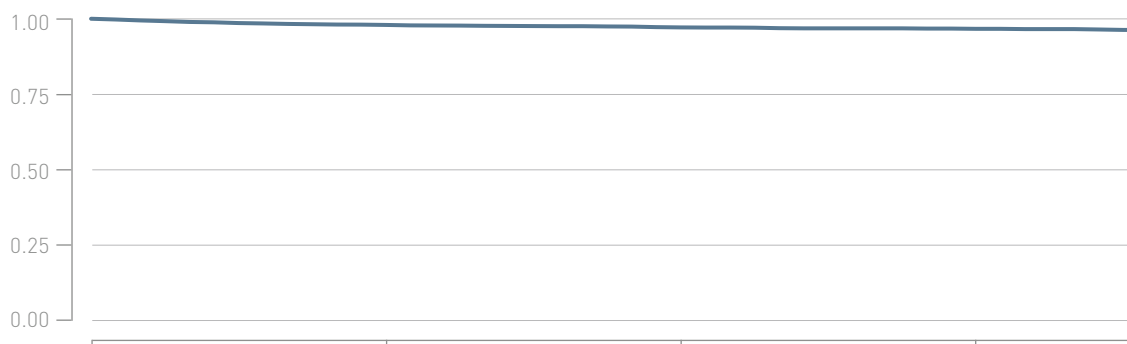
### Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	21 000
Registered U.S. Implants	3 957
Estimated Active U.S. Implants	3 150
U.S. Total Returned	101

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	94	2.33%	<b>U.S. Confirmed Malfunctions</b>	8	0.20%
Abnormal Pacing Impedance	6	0.15%	Conductor Fracture	8	0.20%
Conductor Fracture	1	0.02%			
Extracardiac Stimulation	6	0.15%	<b>U.S. Acute Lead Observations</b>	73	1.81%
Failure to Capture	19	0.47%	Abnormal Pacing Impedance	1	0.02%
Lead Dislodgement	52	1.29%	Extracardiac Stimulation	4	0.10%
Oversensing	9	0.22%	Failure to Capture	9	0.22%
Other	1	0.02%	Failure to Sense	1	0.02%
			Lead Dislodgement	54	1.34%
			Oversensing	3	0.07%
			Other	1	0.02%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	97.8	97.0	96.5
CI [±%]	-	0.5	0.6	0.7
Sample Size	3957	2682	1983	1116



## **Methodology for Lead Survival Estimates Based on Clinical Studies**

- 7.1 Introduction
- 7.2 BIOTRONIK's Clinical Studies
- 7.3 Lead Complications
- 7.4 Lead Product Performance Graphs and Data



# 7. Methodology for Lead Survival Estimates Based on Clinical Studies

## 7.1 Introduction

All leads and lead segments returned to BIOTRONIK are thoroughly analyzed to determine whether or not they meet BIOTRONIK's long term quality standards.

Although analysis of returned product is an excellent method for gaining insight into lead failure mechanisms, this data relies on the return of explanted leads. For the majority of complications the lead is not received for analysis as challenging clinical environments may not allow for the return, e.g. the extraction of an implanted lead may not be possible.

BIOTRONIK includes all reported chronic complications in the calculation of the survival estimates as described in chapter 6, i.e. reports with returned and without returned products.

However, BIOTRONIK can only report events in the survival estimates if those events were reported to BIOTRONIK. In order to eliminate possible biased survival estimates due to underreporting, BIOTRONIK performs clinical surveillance studies with active follow-up's under FDA guidance yielding the most reliable lead performance data.

In the following chapter BIOTRONIK shows – in addition to the survival data based on returned product analysis and chronic complication information – the lead performance data from clinical trials. These studies are designed to record clinical observations representative of the total clinical experience.

## 7.2 BIOTRONIK's Clinical Studies

### 7.2.1 GALAXY and CELESTIAL

BIOTRONIK's GALAXY and CELESTIAL Registries are prospective, non-randomized, observational studies. The key purpose of these registries is to confirm the long-term safety and reliability of BIOTRONIK leads as used in conjunction with a BIOTRONIK ICD (GALAXY) or CRT (CELESTIAL) system. All devices in the registries are legally marketed and available to physicians according to approved FDA indications for use. GALAXY and CELESTIAL Registries are registered on [clinicaltrials.gov](https://clinicaltrials.gov) under NCT00836589 and NCT00810264 respectively.

The evaluation of safety for GALAXY is based on the analysis of BIOTRONIK Linx ICD lead-related adverse events. The evaluation of safety for CELESTIAL is based on the analysis of BIOTRONIK Corox LV pacing lead-related adverse events. However, many CELESTIAL patients also have a Linx ICD lead implanted and the Linx clinical studies data in this report represents combined data from the GALAXY and CELESTIAL registries. Both registries are designed to continue for a 5 year follow-up duration per patient. The GALAXY Registry was completed in December 2016, while CELESTIAL completed in November 2018. The lead-related complication free survival probabilities provided for Corox LV and Linx ICD leads within chapter 8 utilize all data collected through registry closure. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the

range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits per their institutional standard of care until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum of once every six months follow-up requirement.

During each follow up at a study center the following steps are required during the follow-up visit:

- Interrogate programmed parameters
- Determine lead electrical parameters
- Evaluate device diagnostics and programmed parameters to ensure the device is providing appropriate therapy
- Determine if there are any reportable lead-related, pulse generator-related or implant procedure-related adverse events. If there are, complete an adverse event electronic case report form (eCRF)
- Complete all appropriate eCRFs

This active surveillance model ensures a robust dataset for effectively monitoring product performance.

#### Patient Enrollment Criteria

To support the objectives of these registries, participants are required to meet the following inclusion criteria prior to enrollment:

- Successfully implanted BIOTRONIK ICD (GALAXY) or BIOTRONIK CRT (CELESTIAL) system, including the study lead
- Able to understand the nature of the registry and give informed consent
- Available for follow-up visits on a regular basis at the study site
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures, regardless of the incidence rates, are investigated.

### 7.2.2 SIELLO Clinical Study

BIOTRONIK's SIELLO Clinical Study is a prospective, non-randomized, combined Pre-Market Study and Post-Approval Registry designed to demonstrate the safety and effectiveness of the Siello pacing lead as used in conjunction with any market-released BIOTRONIK pacemaker device. The SIELLO Clinical Study is registered on clinicaltrials.gov under NCT01791127.

For the Pre-Market Study, the evaluation of safety is based on the analysis of Siello lead-related adverse events through a follow-up time of 12 months post-implant, while the evaluation of effectiveness is based on analysis of the success rate of the implanted system including one or two Siello leads to sense and deliver pacing at 12 months post-implant.

For the Post-Approval Registry, the evaluation of long-term safety is based on the analysis of Siello lead-related adverse events through a follow-up time of 5 years post-implant. In April 2019, the Siello Post-Approval Registry was converted to utilize real-world data sources as part of the EP PASSION Project (as described in Section 9). The lead-related complication free survival probabilities provided for the Siello lead in Section 8 includes all data collected through study transition. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, with required follow-ups at 3 and 6 months post-implant and every 6 months thereafter.

During each study follow-up visit the following steps are required:

- Interrogate programmed parameters
- Record electrical parameters of the implanted leads. Perform all pacing threshold measurements at 0.4 ms or 0.5 ms pulse width when feasible
- Evaluate device diagnostics, electrical parameters and programmed parameters to ensure the device is correctly pacing and sensing
- Determine if there are any lead-related, pulse generator-related or procedure related adverse events. If any are recorded, complete the Adverse Event eCRF
- Complete all appropriate eCRFs

This active surveillance model ensures a robust dataset for effectively monitoring product performance.

#### Patient Enrollment Criteria

To support the objectives of the study, participants are required to meet the following inclusion criteria prior to enrollment:

- Candidate for de novo implantation of a market-released BIOTRONIK pacemaker system, including one or two Siello leads. Candidate meets recommendation for pacemaker system implant put forth by guidelines of relevant professional societies

- Able to understand the nature of the study and provide informed consent
- Available for follow-up visits on a regular basis at the investigational site for the expected 5 years of follow-up
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures, regardless of the incidence rates, are investigated.

### 7.2.3 QP ExCELS

BIOTRONIK's QP ExCELS Clinical Study is a combined Pre-Market and Post-Approval, non-randomized, multi-center registry designed to confirm the safety and efficacy of BIOTRONIK's Sentus QP leads in a clinical investigation to support regulatory approval as well as a long-term post-approval evaluation of the devices in the United States. The QP ExCELS Clinical Study is registered on [clinicaltrials.gov](https://clinicaltrials.gov) under NCT02290028.

For the Post-Approval Study, the evaluation of safety will be based on the analysis of Sentus QP lead-related adverse events through a follow-up time of 5 years post-implant. In January 2020, the QP ExCELS Clinical Study was converted to utilize real-world data sources as part of the EP PASSION Project (as described in Section 9). The lead-related complication free survival probabilities provided for the Sentus QP lead in Section 8 includes all data collected through study transition. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits per their institutional standard of care until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, which required follow-ups at discharge/wound check, 3 and 6 months post-implant, and every 6 months thereafter.

#### Patient Enrollment Criteria

To support the objectives of the study, participants are required to meet the following inclusion criteria prior to enrollment:

- Standard CRT-D indication according to clinical routine
- De novo implantation or upgrade from existing ICD or pacemaker implant (with no prior attempt at LV lead placement) utilizing a BIOTRONIK CRT-D system with IS4 LV port and Sentus QP LV lead
- Patient is able and willing to complete all routine study visits at the investigational site through 5 years of follow-up
- Patient is able to understand the nature of the clinical investigation and provide written informed consent
- Patient accepts Home Monitoring concept
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures,

regardless of the incidence rates, are investigated.

## 7.3 Lead Complications

The data presented characterizes chronic lead performance by estimating lead-related complication free survival probabilities. Following industry practice, for analysis purposes, the complication criteria, which align with the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", are defined below.

### 7.3.1 GALAXY and CELESTIAL

All reported lead-related adverse events within the GALAXY and CELESTIAL Registries are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation, is classified with at least one of the following event classifications and at least one of the following clinical actions is made. Any Clinical Event without a related Clinical Action is not considered a Qualifying Complication. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

#### Event Classifications

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200- 2,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is 25 – 150 ohms)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically

- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

#### **Clinical Actions**

- Lead surgically abandoned/capped
- Lead electrically abandoned
- Lead explanted
- Lead replaced
- Lead conductor taken out of service
- Lead use continued based on medical judgment despite a known clinical performance issue
- Other lead-related surgery

### **7.3.2 SIELLO**

All reported lead-related adverse events within the SIELLO Clinical Study are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation and is classified with at least one of the following event classifications. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

#### **Event Classifications**

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 - 2,000 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

### **7.3.3 QP ExCELS**

All reported lead-related adverse events within the QP ExCELS registry are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation and is classified with at least one of the following event classifications. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

#### **Event Classifications**

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 - 2,000 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

## **7.4 Lead Product Performance Graphs and Data**

The clinical data presented on the following page is intended to show the long term clinical performance of leads based on clinical studies. The same analysis methods as described in chapter 6 are applied.

#### **Returned Product Analysis Results**

Although the returned product analysis data is not used to generate the survival estimates for the clinical data, it provides valuable insight into the causes of lead malfunction. Following the same approach as for complaint data, a malfunction is reported as described in section 6.3 of this report.



## **Performance of BIOTRONIK Leads Based on Clinical Study Data**

8.1 Performance of Pacing Leads

8.2 Performance of ICD Leads

8.3 Performance of CRT Leads



## **Performance of BIOTRONIK Leads Based on Clinical Study Data**

### **8.1 Performance of Pacing Leads**

#### 8.2 Performance of ICD Leads

#### 8.3 Performance of CRT Leads

## 8.1 Performance of Pacing Leads – Study Data

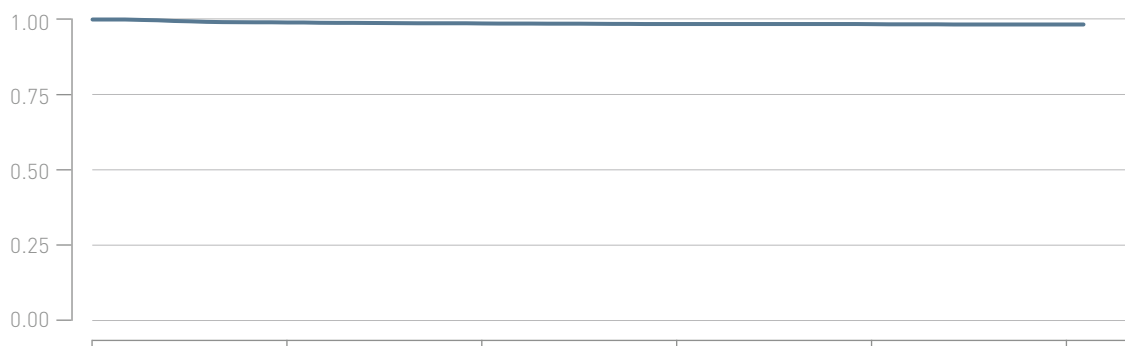
### Siello S / Solia S

Product Versions _____	45, 53, 60
Lead Type _____	straight, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jun 2016
CE Market Release _____	Jul 2009
Worldwide Distributed Devices _____	1 616 000
Registered U.S. Implants _____	3 245

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b> _____	54	1.66%	<b>U.S. Confirmed Malfunctions</b> _____	3	0.09%
Abnormal Pacing Impedance _____	4	0.12%	Conductor Fracture _____	1	0.03%
Cardiac Perforation _____	3	0.09%	Insulation Breach _____	1	0.03%
Conductor Fracture _____	2	0.06%	Other _____	1	0.03%
Failure to Capture _____	23	0.71%			
Failure to Sense (undersensing) _____	11	0.34%	<b>U.S. Acute Lead Observations</b> _____	26	0.80%
Lead Dislodgement _____	9	0.28%	Cardiac Perforation _____	8	0.25%
Oversensing _____	1	0.03%	Extracardiac Stimulation _____	2	0.06%
Other _____	1	0.03%	Failure to Capture _____	6	0.18%
			Failure to Sense (undersensing) _____	5	0.15%
			Lead Dislodgement _____	5	0.15%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.9	98.5	98.3	98.2	98.1
CI [±%]		0.4	0.4	0.5	0.5	0.5
Sample Size	3245	2793	2479	2200	1769	293



## Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads

**8.2 Performance of ICD Leads**

8.3 Performance of CRT Leads

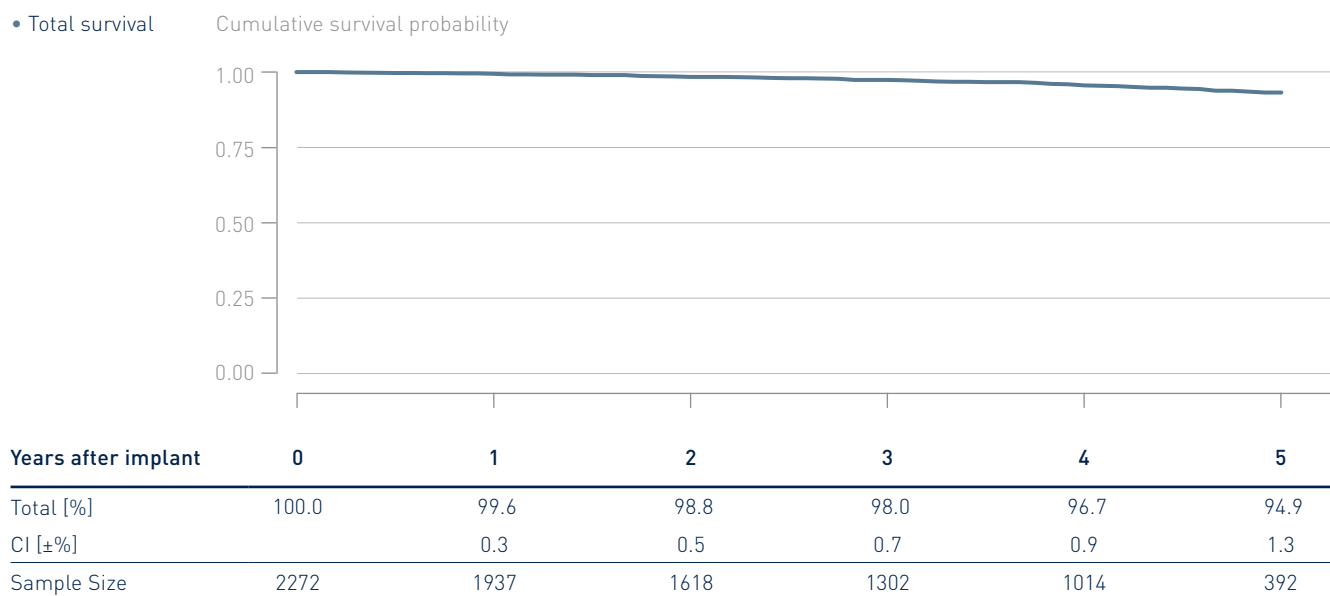


## 8.2 Performance of ICD Leads – Study Data

### Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	2 272

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	68	2.99%	<b>U.S. Confirmed Malfunctions</b>	24	1.06%
Abnormal Defibrillation Impedance	4	0.18%	Conductor Fracture	3	0.13%
Abnormal Pacing Impedance	10	0.44%	Insulation Breach	21	0.92%
Cardiac Perforation	1	0.04%	<b>U.S. Acute Lead Observations</b>	8	0.35%
Conductor Fracture	10	0.44%	Cardiac Perforation	4	0.18%
Failure to Capture	7	0.31%	Conductor Fracture	1	0.04%
Failure to Sense	3	0.13%	Failure to Capture	1	0.04%
Insulation Breach	13	0.57%	Lead Dislodgement	1	0.04%
Lead Dislodgement	3	0.13%	Other	1	0.04%
Oversensing	17	0.75%			



## 8.2 Performance of ICD Leads – Study Data

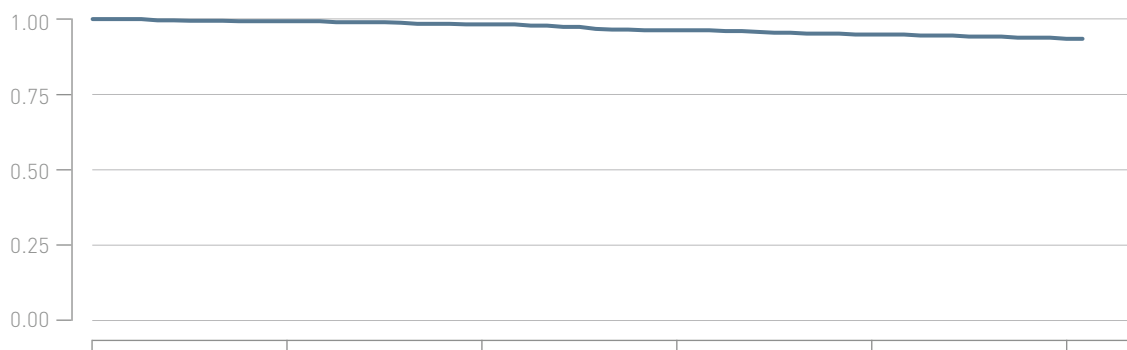
### Linux<sup>smart</sup> SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55700
Registered U.S. Implants	736

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	29	3.94%	<b>U.S. Confirmed Malfunctions</b>	7	0.95%
Abnormal Defibrillation Impedance	2	0.27%	Insulation Breach	7	0.95%
Abnormal Pacing Impedance	2	0.27%			
Conductor Fracture	3	0.41%	<b>U.S. Acute Lead Observations</b>	2	0.27%
Failure to Capture	3	0.41%	Lead Dislodgement	2	0.27%
Insulation Breach	4	0.54%			
Lead Dislodgement	6	0.82%			
Oversensing	9	1.22%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.3	98.2	96.2	94.8	93.3
CI [±%]		0.7	1.1	1.7	2.1	2.5
Sample Size	736	607	493	373	287	118



## Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads

8.2 Performance of ICD Leads

**8.3 Performance of CRT Leads**

## 8.3 CRT Leads Performance – Study Data

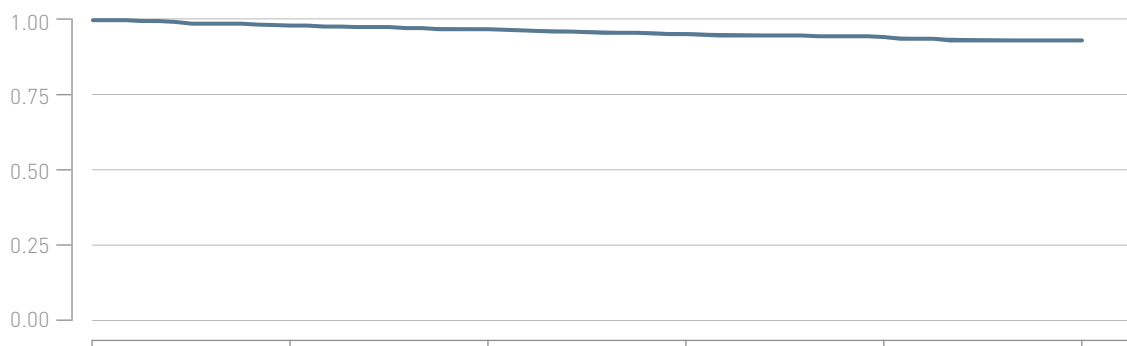
### Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Leads registered in study	696

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	35	5.03%	<b>U.S. Confirmed Malfunctions</b>	6	0.86%
Abnormal Pacing Impedance	6	0.86%	Conductor Fracture	6	0.86%
Conductor Fracture	5	0.72%	<b>U.S. Acute Lead Observations</b>	4	0.57%
Extracardiac Stimulation	3	0.43%	Extracardiac Stimulation	1	0.14%
Failure to Capture	5	0.72%	Lead Dislodgement	3	0.43%
Lead Dislodgement	16	2.30%			

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	96.9	95.2	94.2	93.0
CI [±%]		1.1	1.4	1.8	2.1	2.3
Sample Size	696	589	489	407	329	135

## 8.3 CRT Leads Performance – Study Data

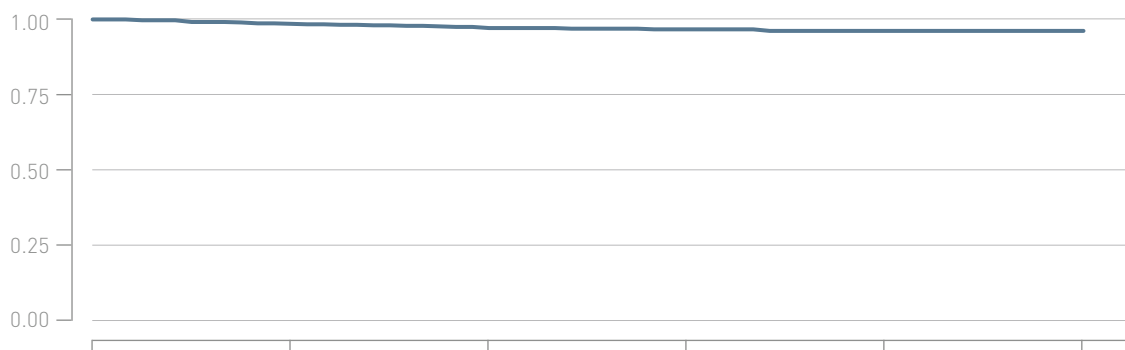
### Corox OTW-L BP

Product Versions _____	75, 85
Lead Type _____	dual-curve fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jan 2011
CE Market Release _____	Dec 2009
Worldwide Distributed Devices _____	32 000
Leads registered in study _____	699

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b> _____	22	3.15%	<b>U.S. Confirmed Malfunctions</b> _____	0	0.00%
Extracardiac Stimulation _____	4	0.57%			
Failure to Capture _____	8	1.14%	<b>U.S. Acute Lead Observations</b> _____	4	0.57%
Lead Dislodgement _____	10	1.43%	Extracardiac Stimulation _____	3	0.43%
			Lead Dislodgement _____	1	0.14%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.0	96.5	96.0	96.0
CI [±%]		1.0	1.4	1.6	1.7	1.7
Sample Size	699	584	475	382	303	130

## 8.3 CRT Leads Performance – Study Data

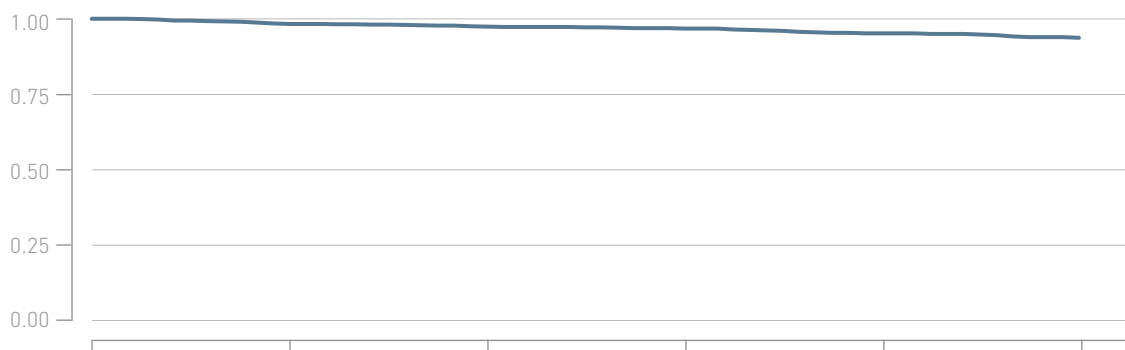
### Corox OTW-S BP

Product Versions _____	75, 85
Lead Type _____	thread fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	26 400
Leads registered in study _____	1 141

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b> _____	49	4.29%	<b>U.S. Confirmed Malfunctions</b> _____	1	0.09%
Abnormal Pacing Impedance _____	13	1.14%	Insulation Breach _____	1	0.09%
Extracardiac Stimulation _____	9	0.79%			
Failure to Capture _____	9	0.79%	<b>U.S. Acute Lead Observations</b> _____	5	0.44%
Lead Dislodgement _____	18	1.58%	Extracardiac Stimulation _____	1	0.09%
			Failure to Capture _____	1	0.09%
			Lead Dislodgement _____	3	0.26%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	97.3	96.6	95.0	93.5
CI [±%]		0.8	1.0	1.2	1.5	1.9
Sample Size	1141	963	813	648	505	192

## 8.3 CRT Leads Performance – Study Data

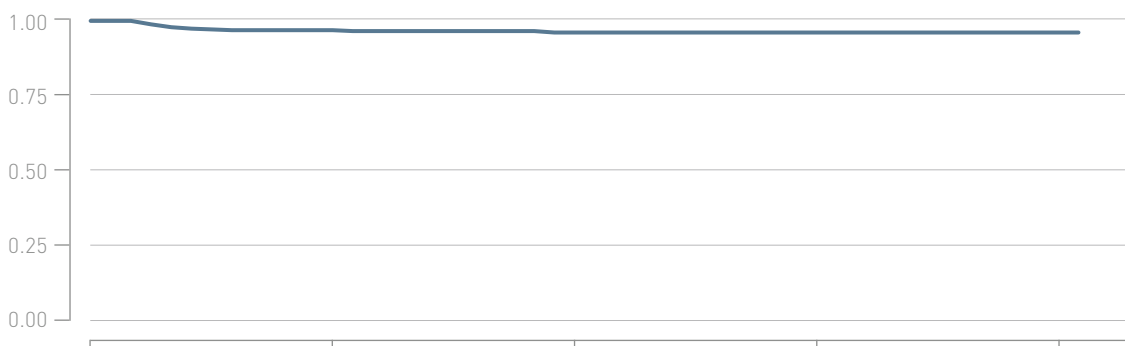
### Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	21 000
Registered U.S. Implants	436

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	15	3.44%	<b>U.S. Confirmed Malfunctions</b>	2	0.46%
Conductor Fracture	1	0.23%	Conductor Fracture	2	0.46%
Extracardiac Stimulation	1	0.23%			
Failure to Capture	3	0.69%	<b>U.S. Acute Lead Observations</b>	10	2.29%
Lead Dislodgement	10	2.29%	Cardiac Perforation	1	0.23%
			Failure to Capture	1	0.23%
			Lead Dislodgement	8	1.83%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	96.7	95.9	95.9	95.9
CI [±%]		1.8	2.2	2.2	2.2
Sample Size	436	299	170	55	0

## 8.3 CRT Leads Performance – Study Data

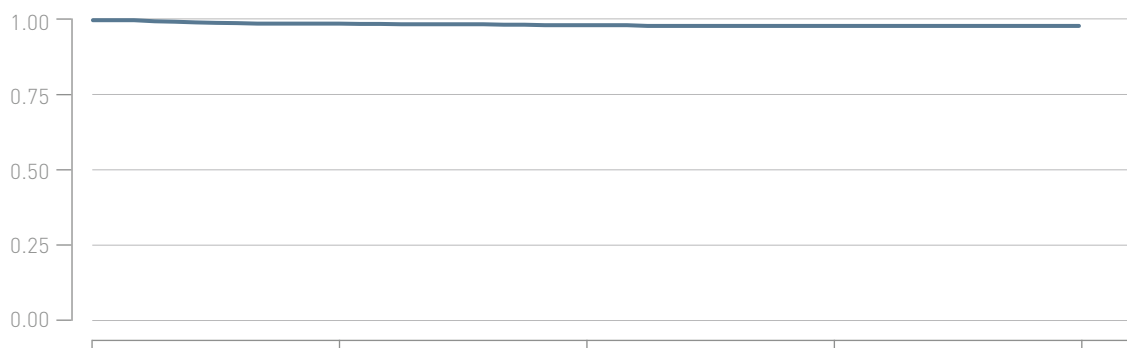
### Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	95 800
Registered U.S. Implants	1 308

	Quantity	Rate		Quantity	Rate
<b>U.S. Qualifying Complications</b>	21	1.61%	<b>U.S. Confirmed Malfunctions</b>	8	0.61%
Abnormal Pacing Impedance	3	0.23%	Conductor Fracture	7	0.54%
Conductor Fracture	1	0.08%		1	0.08%
Extracardiac Stimulation	2	0.15%	<b>U.S. Acute Lead Observations</b>	7	0.54%
Failure to Capture	4	0.31%	Extracardiac Stimulation	1	0.08%
Lead Dislodgement	11	0.84%	Failure to Capture	4	0.31%
			Lead Dislodgement	2	0.15%

#### • Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	98.7	98.1	97.9	97.9
CI [±%]		0.7	0.9	1.1	1.1
Sample Size	1308	863	418	138	0





# **Methodology for Lead Survival Estimates based on Insurance Claims Data**

9.1 Introduction

9.2 Claims Data Methodologies  
and Data Sets

## 9. Methodology for Lead Survival Estimates based on Insurance Claims Data

### 9.1 Introduction

All leads and lead segments returned to BIOTRONIK are thoroughly analyzed to determine whether or not they meet BIOTRONIK's long term quality standards. Although analysis of returned product is an excellent method for gaining insight into lead failure mechanisms, this data relies on the return of explanted leads. For the majority of complications the lead is not received for analysis as challenging clinical environments may not allow for the return, e.g. the extraction of an implanted lead may not be possible.

BIOTRONIK includes all reported chronic complications in the calculation of the survival estimates as described in chapter 5, i.e. reports with returned and without returned products. However, BIOTRONIK can only report events in the survival estimates if those events were reported to BIOTRONIK. In order to eliminate possible biased survival estimates due to underreporting, active surveillance methodologies utilizing extant real-world data sources have been developed in collaboration with FDA and other key stakeholders under the Device Pilot Project EP PASSION, established under Section 708 of the FDA Reauthorization Act of 2017 (FDARA). Identical methodology is being applied to the analysis provided in this PPR.

In the following chapter BIOTRONIK shows – in addition to the survival data based on returned product analysis and chronic complication information from customer reported complaints as well as clinical studies – the lead performance data from active surveillance of real-world data sources. These analyses are designed to record clinical observations representative of the total real-world clinical experience.

### 9.2 Claims Data Methodologies and Data Sets

To perform real-world analysis, insurance claims data obtained via the Centers for Medicare and Medicaid Services (CMS), as well as data from BIOTRONIK's device tracking database, are utilized to identify lead-related complications. As the source of the claims data is CMS, the U.S. federal health insurance program, the analysis is limited to the sub-set of patients with a device implant that receive benefits through CMS with coverage that was active at the time of device implant. Diagnosis and procedure codes from CMS insurance claims that correspond to lead-related complications are identified and each event is evaluated to identify the related system component(s). This approach combines the advantages from passive complaint reporting (large device populations) with the advantage from clinical studies (reliable, consistent reporting) to ensure statistically sound device performance figures. However, due to the nature of insurance claims, fewer details of the device complications are known.

As part of the Device Pilot Project EP PASSION, the real-world methodology developed in collaboration with the stakeholders was validated in a proof of concept analysis. Results demonstrated high agreement of 99.7% between the real-world data outcomes and results from a prospective study. Based on the proof of concept results, BIOTRONIK received FDA approval to utilize this methodology to fulfil post-approval reporting requirements for both low and high voltage leads.

For PPR analysis, the complication criteria are aligned with the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse

Generators and Leads". Specifically, the codes identify lead-related complications that would result in a cardiac lead being removed or replaced, or result in a new lead being implanted as a result of the lead-related complication. Identified complications are limited to events with an onset date of more than 30 days after implant. Acute complications, those with an onset date of 30 days or less after implant, are excluded from analysis.

To protect patient confidentiality, CMS restricts direct reporting of data cell values of 1 to 10. Therefore, lead models with 10 or less identified complications will not be reported within the PPR. In addition, lead models that are no longer distributed with less than 500 leads available for analysis are excluded.

#### Lead Tracking and Reporting

Patients implanted with a BIOTRONIK lead after U.S. market approval as identified in BIOTRONIK's U.S. device registration system are directly linked with CMS beneficiary information and claims data. The claims datasets will be updated for each Product Performance Report. Lead-related complications identified from CMS claims data and identified to be related to the BIOTRONIK leads are reported. The overall lead-related complication rate by lead model is provided.

In order to provide statistically sound data, sample sizes of less than 100 subjects are not reported.

1 Hicks J, Keith M, Moll P, Simeles J, Offer E, Diani C, Rock A, and Mitchell K. Novel Method to Identify Lead Complications in Pacemaker Systems from Real-World Data: Proof of Concept for the Siello S Pacing Lead. Heart Rhythm. 2019; 16(5), Supplement, S-P003-089.



## **Performance of BIOTRONIK Leads Based on Insurance Claims Data**

10.1 Pacing Leads Performance –  
Insurance Claims Data

10.2 ICD Leads Performance –  
Insurance Claims Data



## **Performance of BIOTRONIK Leads Based on Insurance Claims Data**

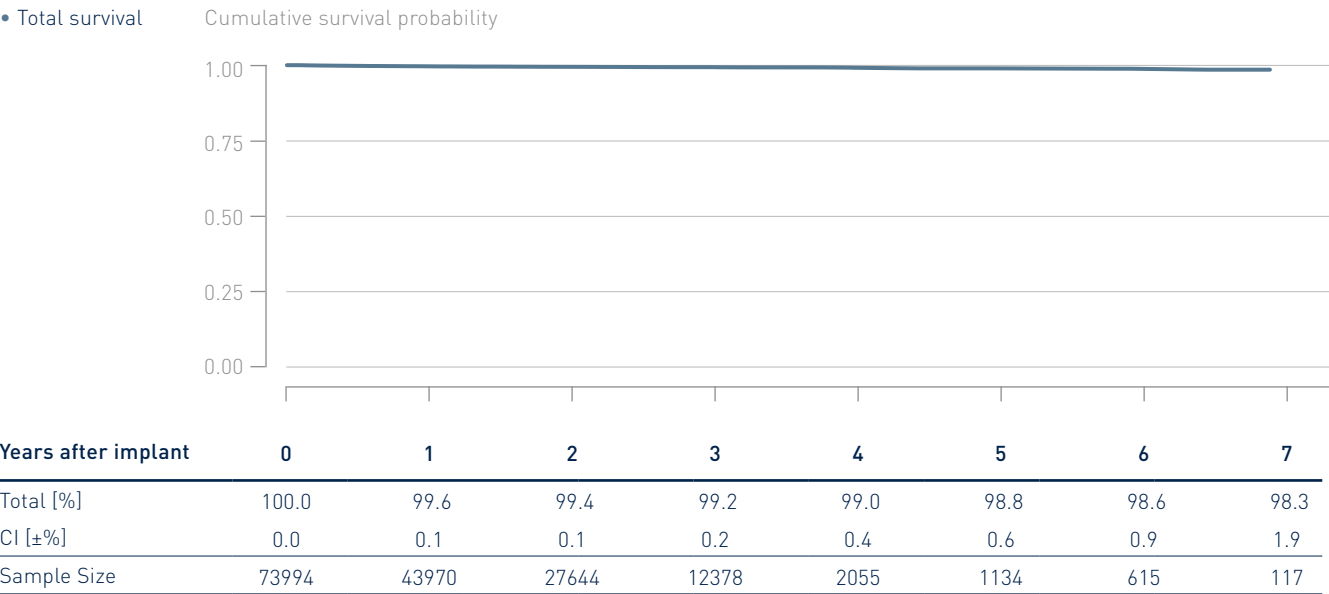
**10.1 Pacing Leads Performance –  
Insurance Claims Data**

10.2 ICD Leads Performance –  
Insurance Claims Data

10.1 Pacing Leads Performance – Insurance Claims Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2013
CE Market Release	Feb 2009
Worldwide Distributed Devices	1 942 000
Registered U.S. Implants	73 994





## **Performance of BIOTRONIK Leads Based on Insurance Claims Data**

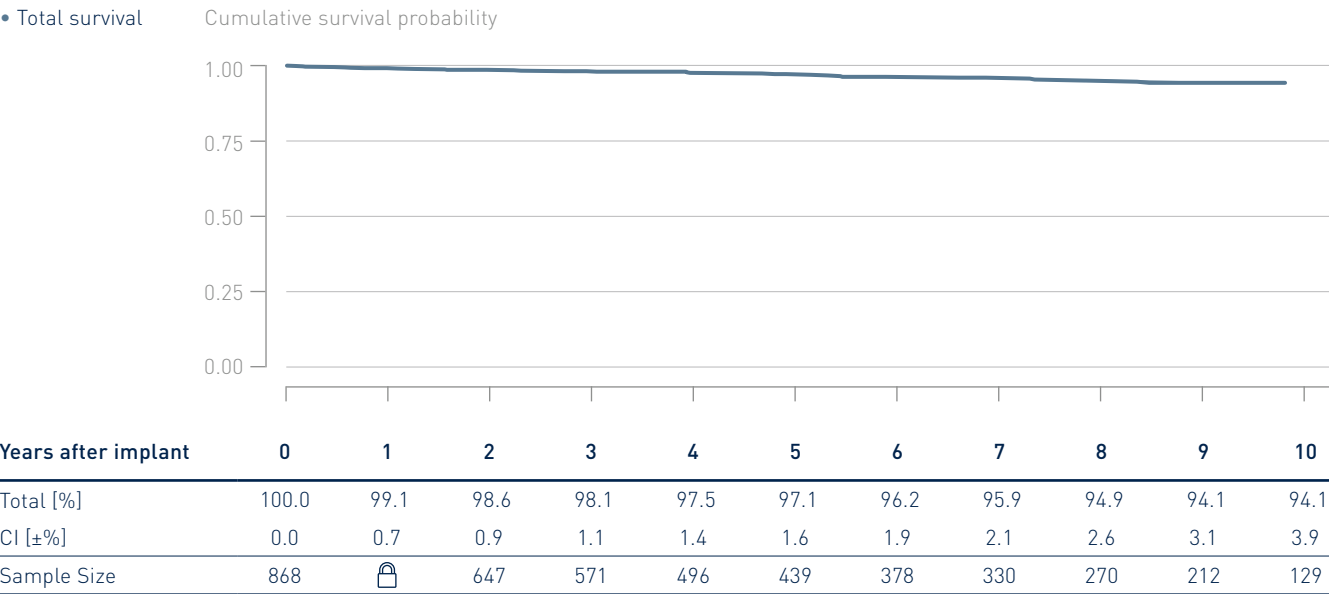
10.1 Pacing Leads Performance –  
Insurance Claims Data

**10.2 ICD Leads Performance –  
Insurance Claims Data**

10.2 ICD Leads Performance – Insurance Claims Data

Linux S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	868

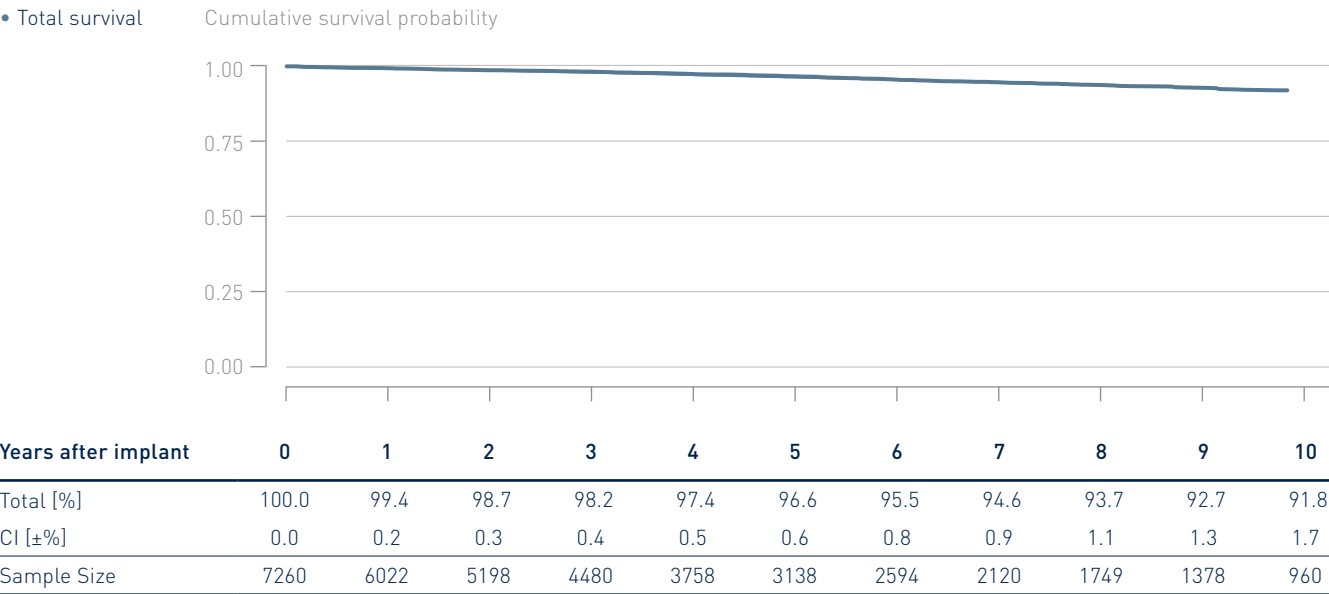


🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	7 260

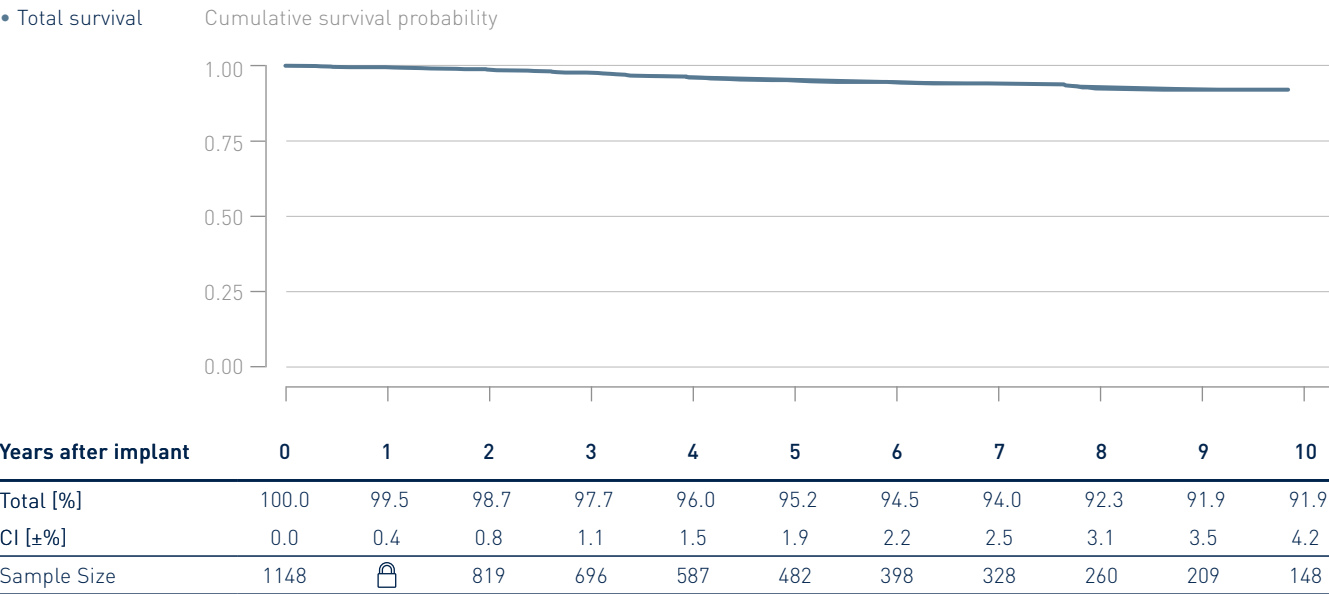




10.2 ICD Leads Performance – Insurance Claims Data

Linux TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered U.S. Implants	1 148

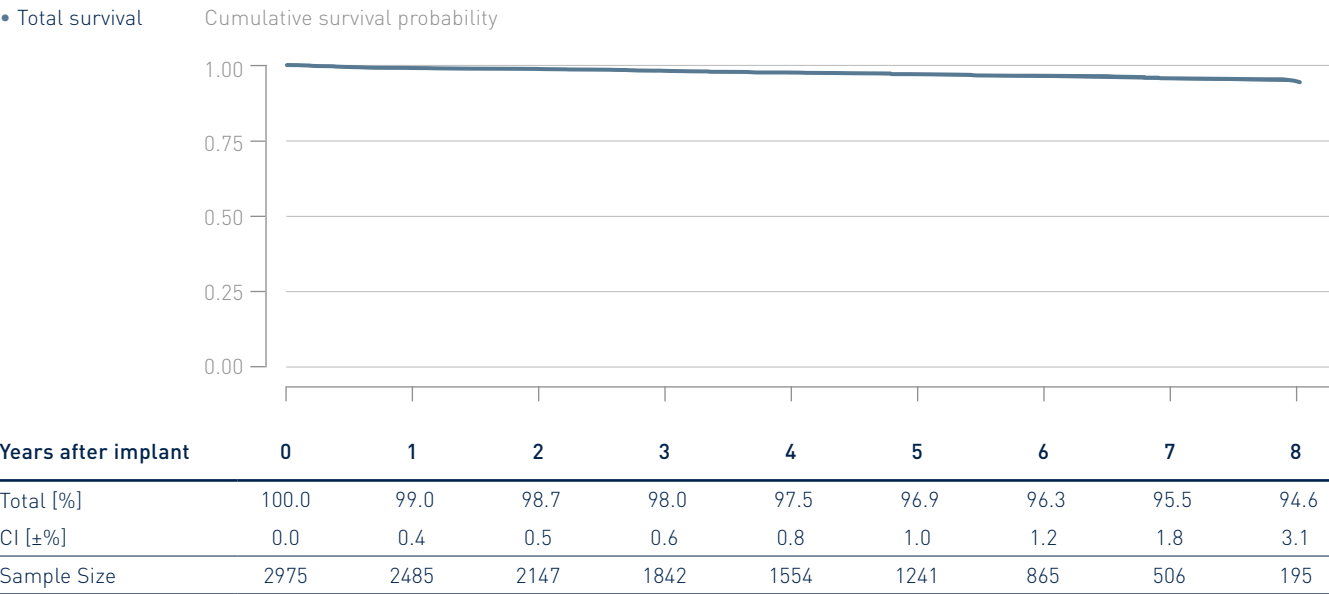


cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux<sup>Smart</sup> S

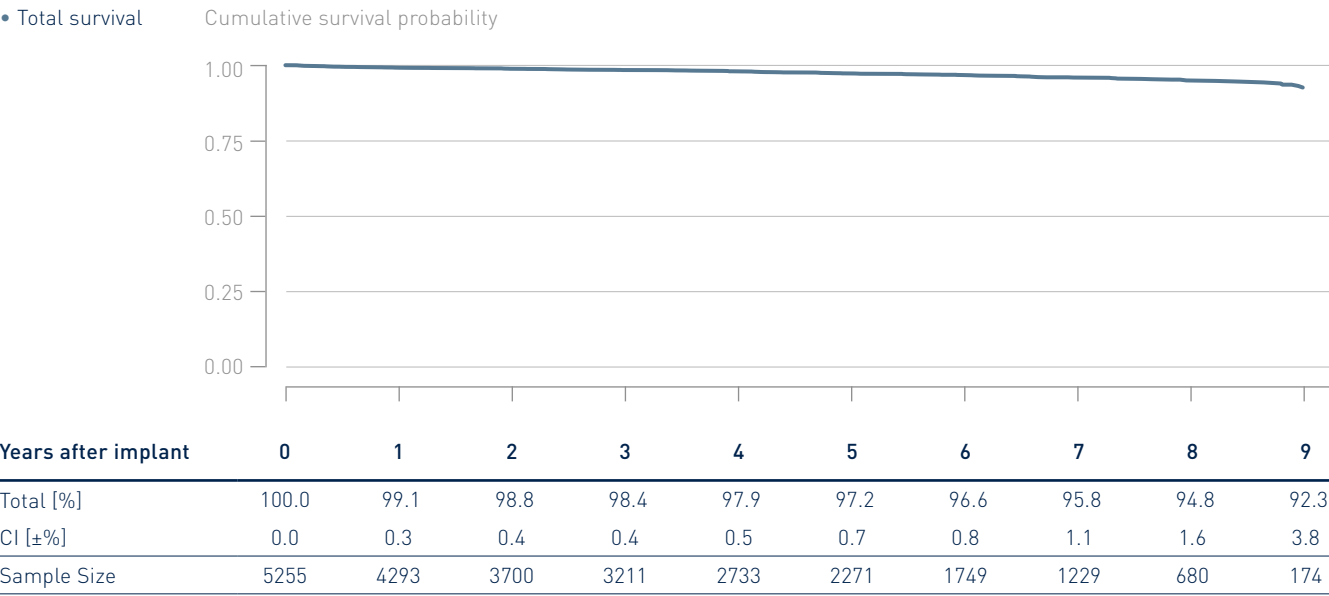
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	2 975



10.2 ICD Leads Performance – Insurance Claims Data

Linux<sup>Smart</sup> SD

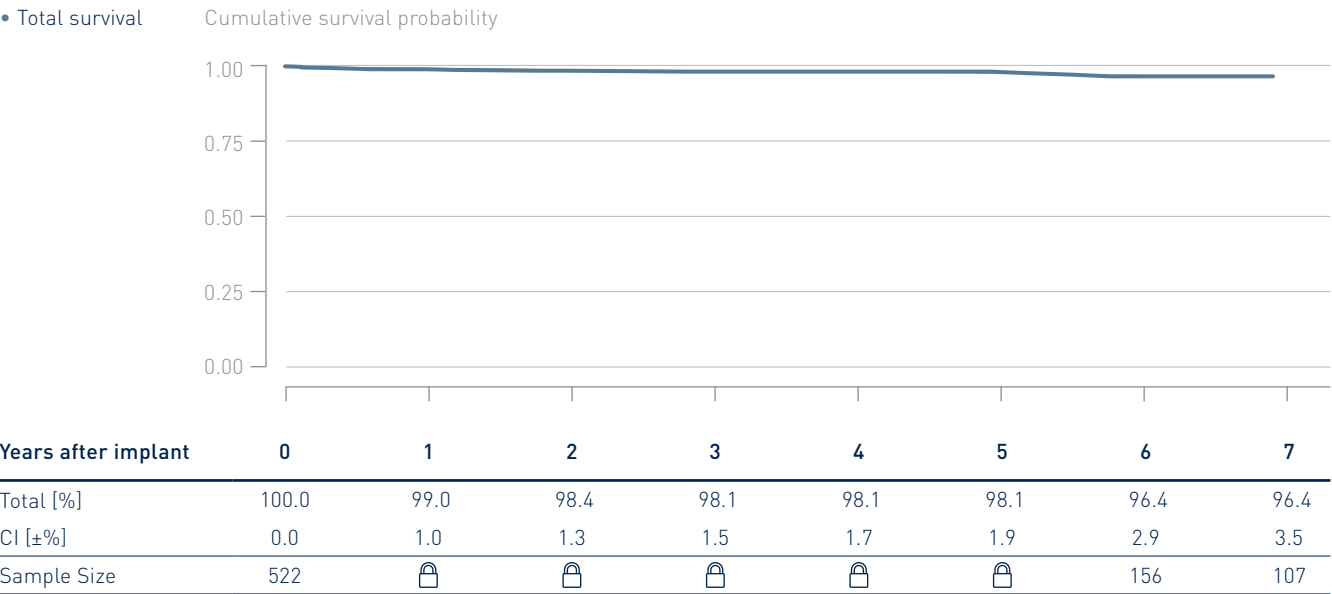
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	5 255



10.2 ICD Leads Performance – Insurance Claims Data

Linux<sup>Smart</sup> TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered U.S. Implants	522

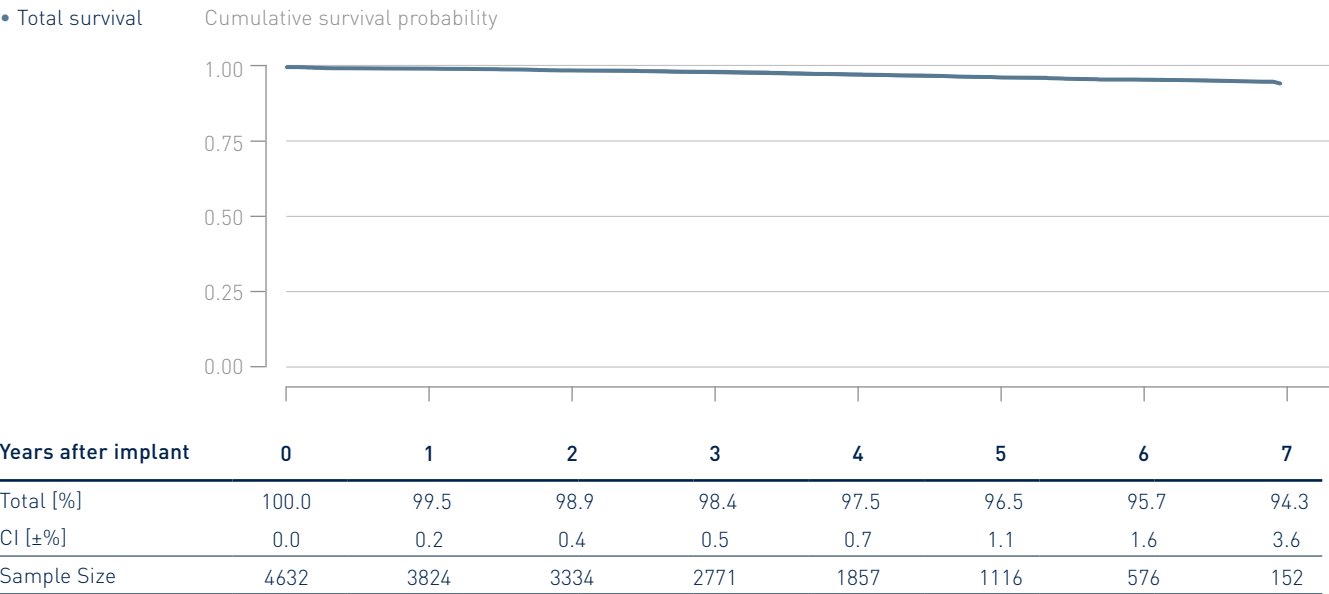


🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux<sup>Smart</sup> S DX

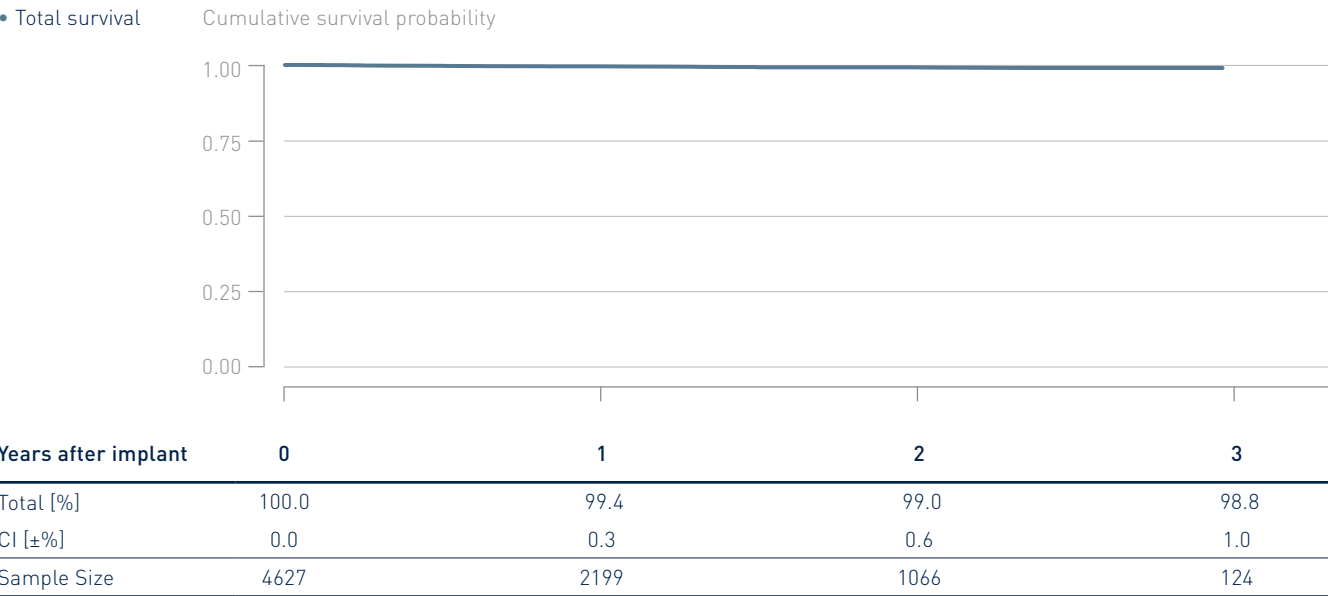
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	4632



10.2 ICD Leads Performance – Insurance Claims Data

Plexa S

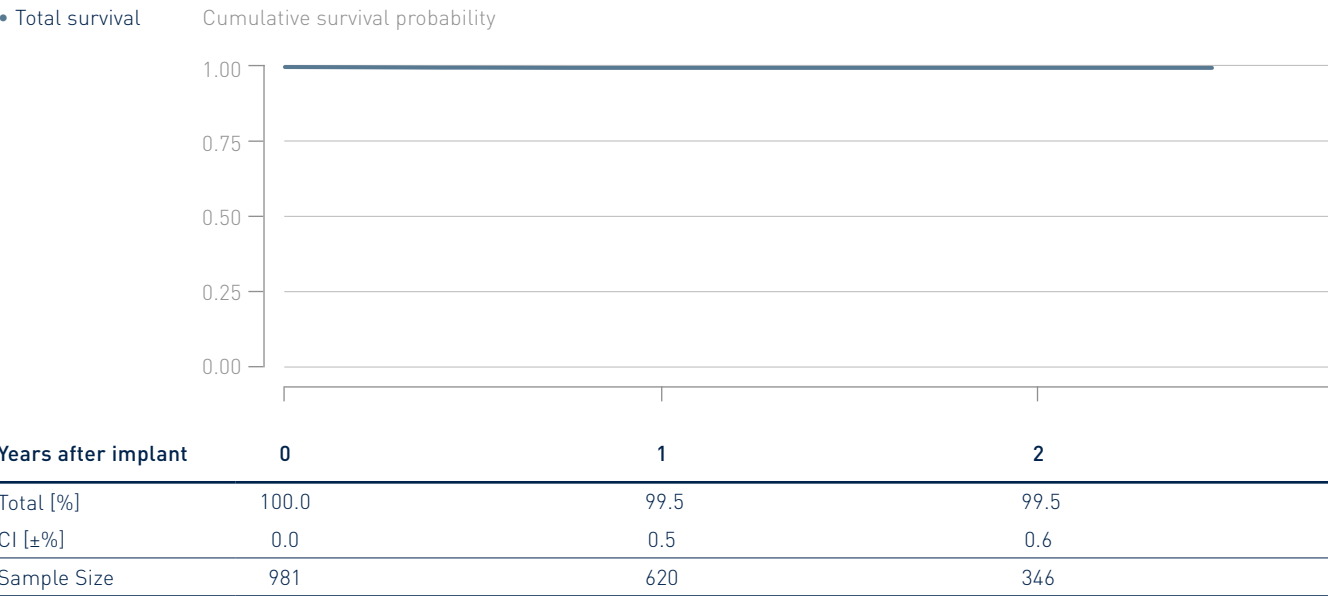
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	95 600
Registered U.S. Implants	4 627



10.2 ICD Leads Performance – Insurance Claims Data

Plexa SD

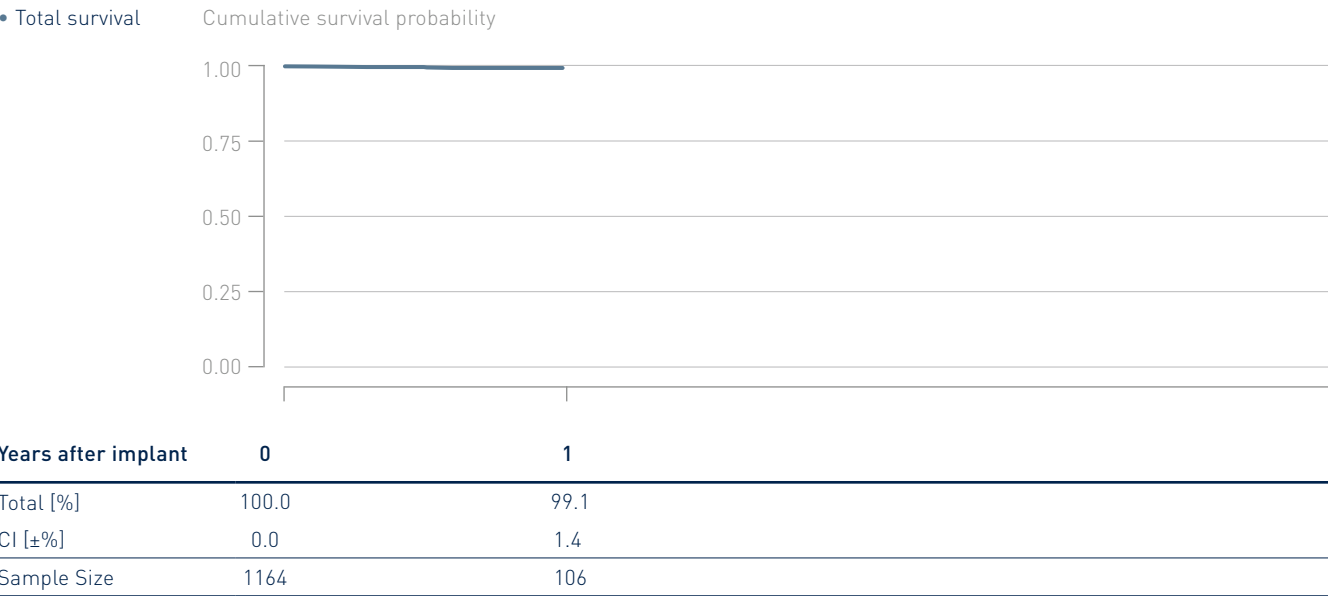
Product Versions	60/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	11 000
Registered U.S. Implants	981



10.2 ICD Leads Performance – Insurance Claims Data

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	14 100
Registered U.S. Implants	1 164

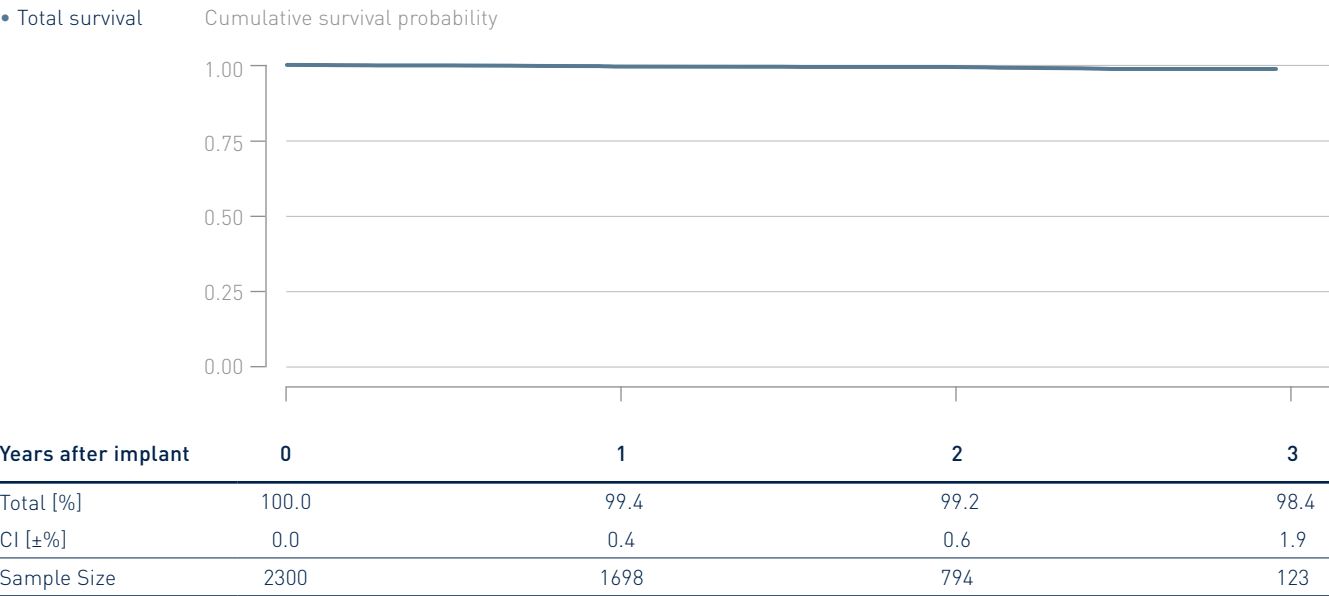




10.2 ICD Leads Performance – Insurance Claims Data

Plexa S DX DF1

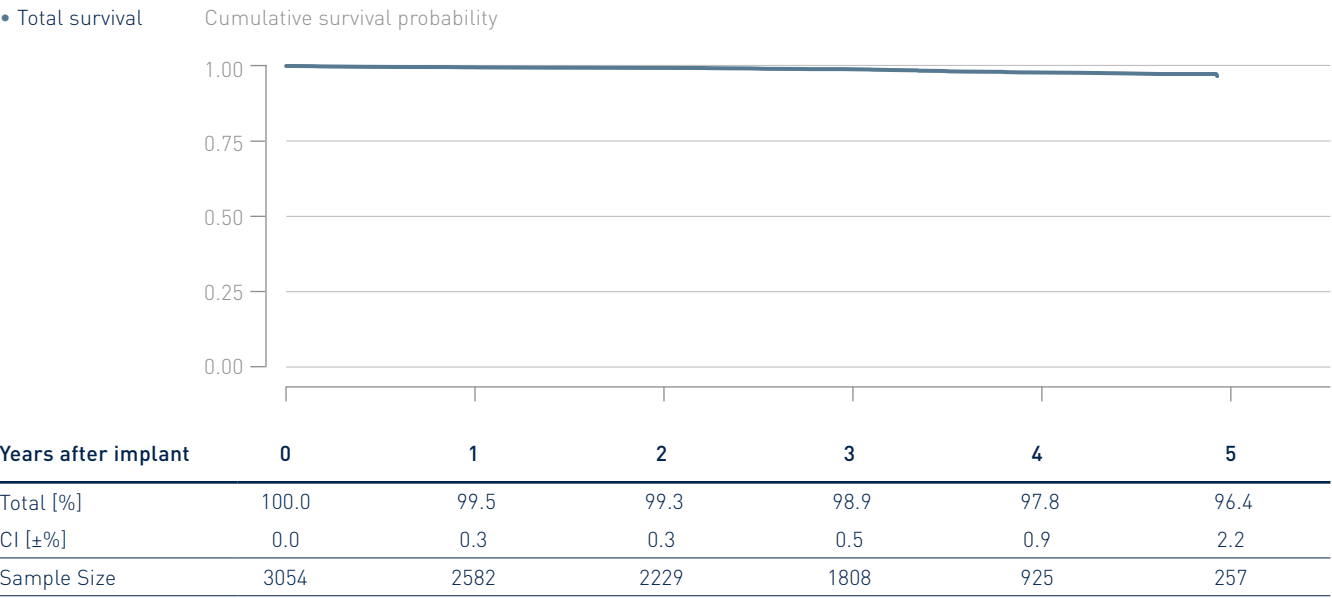
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	20 600
Registered U.S. Implants	2 300



# 10.2 ICD Leads Performance – Insurance Claims Data

## Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	3 054





## Advisories

# 11. Advisories

## BIO-LQC Potential premature battery depletion in a subset of ICD and CRT-D devices 162,000 devices world-wide, 38,000 in the United States

### Status Update

FDA has classified this advisory as a class II recall.

The updated software version 2100 or later is available. It has been released on April 30th, 2021 in the United States. The corresponding CE-Version has been released on March 31st, 2021.

Since the start of the FSCA the distribution of all devices with an affected battery has been immediately stopped. All data of returned and analyzed devices have been carefully assessed to provide a comprehensive update to the FSN.

As of March 2022

- The cumulative failure rate is 0.57%
- No failures for devices with less than 2 years of implant duration have been reported.
- The failure probability after 2 years remains constant at 0.0012%. The failure probability after 5 years of implant is 0.5%
- One event has been reported with patient death related to early battery depletion after the patient was lost to follow-up for two years. All other events are associated with an additional replacement surgery only.
- Availability of therapy has been assessed for all returned devices to update risk estimation for loss of therapy depending on the service time:

### Risk for loss of pacing therapy

Service Time	Risk per month for loss of pacing
0 – 24 months	< 0.00001%
24 – 48 months	0.0012%
48 – 72 months	0.0090%

### Risk for loss of high-voltage therapy

Service Time	Risk per month for loss of shock therapy
0 – 24 months	< 0.00001%
24 – 48 months	0.0020%
48 – 72 months	0.0146%

### Original communication: March 2021

BIOTRONIK has become aware of an increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators ("ICDs") and Cardiac Resynchronization Therapy Defibrillators ("CRT-Ds").

Idova, Iforia, Ilesto  
Inventra, Iperia, Itrevia  
Ilivia, Inlexa, Intica  
Ilivia Neo, Intica Neo ICDs and CRT-Ds

These devices have been distributed since 2013. Please note that not all devices of the above models are affected, nor are other ICD or CRT-D families.

We have received no reports of serious injury or death associated with this issue. To date, all reports describe devices that fell short of expected longevity, resulting in an earlier than expected need for device exchange.

### Reason for this Communication

The current observed rate of confirmed premature battery depletion events is 0.1% of all devices susceptible to this issue. Since every case of battery depletion may not be reported to BIOTRONIK, the exact number of devices that have experienced this issue is not entirely

known. BIOTRONIK estimates the number of active devices which are potentially susceptible to this issue to be approximately 162,000 worldwide.

Analyses of returned devices has revealed the potential for a certain mode of lithium deposition on the anodes of the batteries, known as lithium plating, to occur.

Lithium plating is a very rare phenomenon that may cause a battery drain at a higher rate than under typical use.

The observed onset for devices experiencing this issue is about 2 years with a failure rate of 0.0012%. The projected failure rate at 5 years after implantation is estimated to be 0.17%

### Risk to Health

There is a very low risk that premature battery depletion could result in sudden loss of high-voltage or pacing therapy. Analyses of returned devices indicate that the risk for loss of high-voltage therapy is 0.0069% and the risk for loss of pacing therapy is 0.0015% on a per month basis. Due to the identified issue, the interval between the elective replacement indicator ("ERI") being triggered and the loss of ability to provide therapy may be shorter than expected. Our records show, that for impacted devices, the median interval from ERI to loss of high-voltage therapy was 58 days. The median interval until loss of pacing therapy was 6 months.

### Early Battery Failure Detection

By design, BIOTRONIK's programmer and Home Monitoring system are equipped with a battery depletion detector. This feature allows a battery depletion, including any premature depletion, to be detected early and displayed by an ERI during in-office follow-up, or via daily remote

# 11. Advisories

monitoring using BIOTRONIK Home Monitoring.

## Patient Management

### Recommendations

Following a consultation with our medical advisory board, BIOTRONIK recommends you consider the following management options:

- Devices in stock: Do not implant any potentially affected devices, which include all models identified in this communication. Local BIOTRONIK representatives will replace affected devices in hospital inventory.
- Continue with the standard patient follow-up schedule.
  - During follow-ups: Verify the status of the device and battery during in-office or Home Monitoring follow-ups. Please note that unresponsive devices or those that are not transmitting data may be experiencing this issue and your BIOTRONIK representative should be informed if you observe any unusual device behavior.
  - Home Monitoring should be utilized whenever possible as it provides timely ERI warnings to reduce the risk of sudden loss of therapy. If you do not yet use Home Monitoring, please consider if this option is appropriate for you and your patients. BIOTRONIK will provide CardioMessenger devices free of charge to monitor implants affected by this advisory.

If you would like to register for Home Monitoring, please contact your local BIOTRONIK representative. Also, visit [www.biotronik.com/en-de/products/home-monitoring](http://www.biotronik.com/en-de/products/home-monitoring) for further information about Home Monitoring and how it can help you with remote monitoring of your patients in daily practice.

- If there is an unexpected ERI notification for a device that is subject to this advisory, a timely replacement should be considered based on the patient's underlying conditions:
  - For patients that are not pacemaker dependent, or patients with a primary prevention ICD, device replacement within one week after ERI notification is recommended.
  - For pacemaker dependent patients, replacement of the device is recommended immediately after ERI notification.

In consultation with our medical advisory board, BIOTRONIK does not recommend prophylactic replacement. The risk of complications for ICD exchange<sup>1,2,3</sup> outweighs the risk associated with this issue. We refer to the above patient management recommendations in case an unexpected ERI is observed.




We recognize that individual patients have unique clinical needs. Ultimately, patient care—including the frequency of follow-ups—is determined by the physician's clinical judgement, based on individual patient circumstances.

<sup>1</sup> McCarthy KJ, Locke AH, Coletti M, Young D, Merchant FM, Kramer DB. Outcomes Following Implantable Cardioverter-Defibrillator Generator Replacement in Adults: A Systematic Review. *Heart Rhythm*. 2020. [median: 4.57% for complications including reoperation]

<sup>2</sup> Biffi M, Ammendola E, Menardi E, et al. Real-life outcome of implantable cardioverter-defibrillator and cardiac resynchronization defibrillator replacement/upgrade in a contemporary population: Observations from the multicentre DECODE registry. *Europace*. 2019;21(10):1527-1536. [4.4% patients needed at least one surgical action to treat an adverse event following device replacement]

<sup>3</sup> Lewis KB, Stacey D, Carroll SL, Boland L, Sikora L, Birnie D. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. *Pacing and clinical electrophysiology : PACE*. 2016;39(7). [median rates: 4.0% major complications, 3.5% minor complications]

# X-Ray Identifiers for Pacemakers and ICDs

Pacemaker/ICD Product Versions	X-Ray ID
Acticor 7 VR-T DX, HF-T	
Cylos DR, DR-T, VR	RZ
Cylos 990 DR, DR-T, VR	FV
Edora 8 DR, DR-T, SR, SR-T, HF-T	
Entovis DR, DR-T, SR, SR-T	SF
Eluna 8 DR, DR-T	SF
Estella SR, SR-T, DR, DR-T	SF
Etrinsa 8 SR-T, DR-T, HF-T	SF
Evia DR, DR-T, SR, SR-T, HF, HF-T	SF
Iforia 7 VR-T DX, DR-T	NT
Ilesto 7 DR-T, HF-T, VR-T DX, VR-T, DR-T DF4	NT
Ilivia 7 VR-T, DR-T, DR-T DF4, VR-T DX, VR-T DF4, HF-T DF4	NK
Intica 7 VR-T DX, HF-T	NK
Inventra 7 VR-T DX, HF-T DF4	AH
Iperia 7 VR-T, DR-T, VR-T DX, VR-T DF4, HF-T DF4	NH
Itrevia 7 VR-T, DR-T, VR-T DX, DR-T DF4, HF-T, HF-T DF4	NH
Lumax 340 DR-T, HF-T, VR-T	HR
Lumax 540 DR-T, HF-T, VR-T	SH
Lumax 740 DR-T, HF-T, VR-T, VR-T DX	RH
Philos II DR, D, S, SLR, SR	ET
Philos II DR-T	KP
Rivacor 7 DR-T, HF-T, VR-T DF4	
Talos DR, D, SLR, SR, S	PV

# Contacting BIOTRONIK

## Regarding this Report

BIOTRONIK invites your suggestions and questions related to this Product Performance Report. Please send your comments to:

### **PPR Support Team**

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**Fax** +49 (0) 30 68905 96 1920

**E-mail** PPR@biotronik.com

### **Address**

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Attn: Quality Patient Safety  
Woermannkehre 1  
12359 Berlin, Germany

## Regarding Products

BIOTRONIK invites customers to call the following locations with suggestions, comments or specific questions related to BIOTRONIK products:

### **CRM Technical Service**

**Phone** +49 (0) 30 689 05 2200

**Fax** +49 (0) 30 689 05 96 2200

**Email** technical.services@biotronik.com

### **Address**

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Woermannkehre 1  
12359 Berlin, Germany

## Within the U.S.:

**Phone** (800) 547 0394

**Fax** (800) 451 8529

**E-mail** advancedproductsupport@biotronik.com

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Attn: Advanced Product Support  
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Lake Oswego, OR 97035